Australian Government
Department of Health

PBS

Schedule of Pharmaceutical Benefits

Effective 1 June 2016 - 30 June 2016

This Schedule is also available at www.pbs.gov.au

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Contents

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 June 2016 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	$6.93
	Dangerous drug fee	$2.91
	Extemporaneously-prepared	$8.97
	Allowable additional patient charge*	$4.33
Additional Fees (for safety net prices):	Ready-prepared	$1.17
	Extemporaneously-prepared	$1.53
Patient Co-payments:	General	$38.30
	Concessional	$6.20
Safety Net Thresholds:	General	$1475.70
	Concessional	$372.00
Safety Net Card Issue Fee:		$9.61

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

Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 June 2016. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

Prescriber Bag

Additions

Addition – Item

10786Q **NALOXONE**, naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules *(Naloxone Hydrochloride (DBL))*

Deletions

Deletion – Item

2200T **NALOXONE**, naloxone hydrochloride 400 microgram/mL injection, 1 x 1 mL syringe *(Naloxone minijet)*

Deletion – Brand

3495Y *APO-Salbutamol Inhaler, TX* – **SALBUTAMOL**, salbutamol 100 microgram/actuation inhalation: pressurised, 200 actuations

General Pharmaceutical Benefits

Additions

Addition – Item

10778G **CEPHALEXIN**, cephalexin 500 mg capsule, 20 *(APO-Cephalexin, Cefalexin Sandoz, Cephalex 500, Cephalexin AN, Cephalexin generichealth, Chem mart Cephalexin, Cilex, Ialex, Ibilex 500, Keflex, Rancef, Terry White Chemists Cephalexin)*

10790X **DICLOXACILLIN**, dicloxacillin 500 mg capsule, 24 *(Distaph 500)*

10777F **DOXYCYCLINE**, doxycycline 100 mg capsule: modified release, 7 *(Doryx, Mayne Pharma Doxycycline)*

10779H **DOXYCYCLINE**, doxycycline 100 mg tablet, 7 *(Doxsig, Doxy-100, Doxycycline AN, Doxylin 100)*

10781K **DOXYCYCLINE**, doxycycline 100 mg tablet, 7 *(Chem mart Doxycycline, Doxycycline Sandoz, GenRx Doxycycline, Terry White Chemists Doxycycline)*

10780J **ERYTHROMYCIN**, erythromycin 250 mg capsule: enteric, 25 *(Eryc, Mayne Pharma Erythromycin)*

10789W **ERYTHROMYCIN ETHYLSUCCINATE**, erythromycin (as ethylsuccinate) 400 mg tablet, 25 *(E-Mycin, E.E.S. 400 Filmtab)*

10788T **FLUCLOXACILLIN**, flucloxacillin 500 mg capsule, 24 *(APO-Flucloxacillin, Flopen, Staphylex 500)*

10782L **FUSIDATE**, fusidate sodium 250 mg tablet, 36 *(Fucidin)*

10783M **NALOXONE**, naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules *(Naloxone Hydrochloride (DBL))*

10787R **NALOXONE**, naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules *(Naloxone Hydrochloride (DBL))* **(Dental)**

10785P **TRIMETHOPRIM**, trimethoprim 300 mg tablet, 7 *(Alprim, Triprim)*

10784N **TRIMETHOPRIM + SULFAMETHOXAZOLE**, trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10 *(Bactrim DS, Resprim Forte, Septrin Forte)*

Addition – Brand

8188Y *Acarbose Mylan, AF* – **ACARBOSE**, acarbose 50 mg tablet, 90

8189B *Acarbose Mylan, AF* – **ACARBOSE**, acarbose 100 mg tablet, 90

8358X *Blooms the Chemist Clopidogrel, IB* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28

9317J *Blooms the Chemist Clopidogrel, IB* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28

9317J *Chem mart Clopidogrel, CH* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28

9317J *Terry White Chemists Clopidogrel, TW* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28

8879H *Inpler, AF* – **EPLERENONE**, eplerenone 25 mg tablet, 30

8880J *Inpler, AF* – **EPLERENONE**, eplerenone 50 mg tablet, 30

5470X *Ondansetron ODT GH, GQ* – **ONDANSETRON**, ONDANSETRON Tablet (orally disintegrating) 4 mg, 4

5472B *Ondansetron ODT GH, GQ* – **ONDANSETRON**, ONDANSETRON Tablet (orally disintegrating) 4 mg, 10

5471Y *Ondansetron ODT GH, GQ* – **ONDANSETRON**, ONDANSETRON Tablet (orally disintegrating) 8 mg, 4

5473C *Ondansetron ODT GH, GQ* – **ONDANSETRON**, ONDANSETRON Tablet (orally disintegrating) 8 mg, 10

9203J *QUETIAPINE-AS XR, RW* – **QUETIAPINE**, quetiapine 200 mg tablet: modified release, 60

9204K *QUETIAPINE-AS XR, RW* – **QUETIAPINE**, quetiapine 300 mg tablet: modified release, 60

9205L *QUETIAPINE-AS XR, RW* – **QUETIAPINE**, quetiapine 400 mg tablet: modified release, 60

9391G *ATELVIA ONCE-A-MONTH, GN* – **RISEDRONATE**, risedronate sodium 150 mg tablet, 1

Addition – Equivalence Indicator

8188Y *Glucobay 50, BN* – **ACARBOSE**, acarbose 50 mg tablet, 90

8189B *Glucobay 100, BN* – **ACARBOSE**, acarbose 100 mg tablet, 90

8879H *Inspra, PF* – **EPLERENONE**, eplerenone 25 mg tablet, 30

8880J *Inspra, PF* – **EPLERENONE**, eplerenone 50 mg tablet, 30

9203J *Seroquel XR, AP* – **QUETIAPINE**, quetiapine 200 mg tablet: modified release, 60

9204K *Seroquel XR, AP* – **QUETIAPINE**, quetiapine 300 mg tablet: modified release, 60

9205L *Seroquel XR, AP* – **QUETIAPINE**, quetiapine 400 mg tablet: modified release, 60

1937Y *Zantac, AS* – **RANITIDINE**, ranitidine 150 mg tablet: effervescent, 30

Deletions

Deletion – Item

9195Y **ENOXAPARIN SODIUM**, enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL ampoules *(Clexane)*

9196B **ENOXAPARIN SODIUM**, enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL ampoules *(Clexane)*

1588N **KETOPROFEN**, ketoprofen 100 mg suppository, 20 *(Orudis)*

5139L **KETOPROFEN**, ketoprofen 100 mg suppository, 20 *(Orudis)* **(Dental)**

2192J **NALOXONE**, naloxone hydrochloride 400 microgram/mL injection, 1 x 1 mL syringe *(Naloxone minijet)*

2196N **NALOXONE**, naloxone hydrochloride 400 microgram/mL injection, 1 x 1 mL syringe *(Naloxone minijet)* **(Dental)**

Deletion – Brand

8511Y *Chem mart Alendronate 70mg, CH* – **ALENDRONATE**, alendronate 70 mg tablet, 4

8511Y *Terry White Chemists Alendronate 70mg, TW* – **ALENDRONATE**, alendronate 70 mg tablet, 4

2390T *Ibimicyn, JU* – **AMPICILLIN**, ampicillin 500 mg injection, 5 vials

3313J *Ibimicyn, JU* – **AMPICILLIN**, ampicillin 500 mg injection, 5 vials **(Dental)**

2977Q *Ibimicyn, JU* – **AMPICILLIN**, ampicillin 1 g injection, 5 vials

3314K *Ibimicyn, JU* – **AMPICILLIN**, ampicillin 1 g injection, 5 vials **(Dental)**

1312C *Chem mart Diltiazem CD, CH* – **DILTIAZEM**, diltiazem hydrochloride 180 mg capsule: modified release, 30

1312C *GenRx Diltiazem CD, GX* – **DILTIAZEM**, diltiazem hydrochloride 180 mg capsule: modified release, 30

1312C *Terry White Chemists Diltiazem CD, TW* – **DILTIAZEM**, diltiazem hydrochloride 180 mg capsule: modified release, 30

1313D *Chem mart Diltiazem CD, CH* – **DILTIAZEM**, diltiazem hydrochloride 240 mg capsule: modified release, 30

1313D *GenRx Diltiazem CD, GX* – **DILTIAZEM**, diltiazem hydrochloride 240 mg capsule: modified release, 30

1313D *Terry White Chemists Diltiazem CD, TW* – **DILTIAZEM**, diltiazem hydrochloride 240 mg capsule: modified release, 30

1524F *Flucil, AS* – **FLUCLOXACILLIN**, flucloxacillin 500 mg injection, 5 vials

5094D *Flucil, AS* – **FLUCLOXACILLIN**, flucloxacillin 500 mg injection, 5 vials **(Dental)**

1453L *Chem mart Gemfibrozil, CH* – **GEMFIBROZIL**, gemfibrozil 600 mg tablet, 60

1453L *GenRx Gemfibrozil, GX* – **GEMFIBROZIL**, gemfibrozil 600 mg tablet, 60

1453L *Terry White Chemists Gemfibrozil, TW* – **GEMFIBROZIL**, gemfibrozil 600 mg tablet, 60

9248R *Chem mart Gemfibrozil, CH* – **GEMFIBROZIL**, gemfibrozil 600 mg tablet, 60

9248R *GenRx Gemfibrozil, GX* – **GEMFIBROZIL**, gemfibrozil 600 mg tablet, 60

9248R *Terry White Chemists Gemfibrozil, TW* – **GEMFIBROZIL**, gemfibrozil 600 mg tablet, 60

8288F *APO-Salbutamol Inhaler, TX* – **SALBUTAMOL**, salbutamol 100 microgram/actuation inhalation: pressurised, 200 actuations

Deletion – Equivalence Indicator

2390T *Austrapen, AL* – **AMPICILLIN**, ampicillin 500 mg injection, 5 vials

3313J *Austrapen, AL* – **AMPICILLIN**, ampicillin 500 mg injection, 5 vials **(Dental)**

1524F *Flubiclox, JU* – **FLUCLOXACILLIN**, flucloxacillin 500 mg injection, 5 vials

5094D *Flubiclox, JU* – **FLUCLOXACILLIN**, flucloxacillin 500 mg injection, 5 vials **(Dental)**

Alterations

Alteration – Authorised Prescriber

		From	*To*
10509D	**TIOTROPIUM**, tiotropium 2.5 microgram/actuation inhalation: solution, 60 actuations *(Spiriva Respimat)*	MP	MP,NP

Alteration – Restriction

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

10036F **ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE**, arachidonic acid and docosahexaenoic acid with carbohydrate containing 200 mg arachidonic acid and 100 mg docosahexaenoic acid oral liquid: powder for, 30 x 4 g sachets *(keyomega)*

5502N **CARBOMER-974**, carbomer-974 0.3% eye gel, 30 x 500 mg unit doses *(Poly Gel)***(Optometrical)**

8514D **CARBOMER-974**, carbomer-974 0.3% eye gel, 30 x 500 mg unit doses *(Poly Gel)*

5503P **CARBOMER-980**, carbomer-980 0.2% eye gel, 10 g *(Optifresh eye gel, PAA, Viscotears)***(Optometrical)**

5504Q **CARBOMER-980**, carbomer-980 0.2% eye drops, 30 x 0.6 mL unit doses *(Viscotears Gel PF)***(Optometrical)**

8384G **CARBOMER-980**, carbomer-980 0.2% eye gel, 10 g *(Optifresh eye gel, PAA, Viscotears)*

8578L **CARBOMER-980**, carbomer-980 0.2% eye drops, 30 x 0.6 mL unit doses *(Viscotears Gel PF)*

9210R **CARBOMER-980**, carbomer-980 0.2% eye gel, 10 g *(Optifresh eye gel, PAA, Viscotears)*

2324H **CARMELLOSE SODIUM**, carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses *(Celluvisc, Optifresh Plus)*

2338C **CARMELLOSE SODIUM**, carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses *(Cellufresh, Optifresh Tears)*

5505R **CARMELLOSE SODIUM**, carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses *(Celluvisc, Optifresh Plus)***(Optometrical)**

5506T **CARMELLOSE SODIUM**, carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses *(Cellufresh, Optifresh Tears)***(Optometrical)**

5509Y **CARMELLOSE SODIUM**, carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses *(TheraTears)***(Optometrical)**

5510B **CARMELLOSE SODIUM**, carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses *(TheraTears)***(Optometrical)**

8823J **CARMELLOSE SODIUM**, carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses *(TheraTears)*

8824K **CARMELLOSE SODIUM**, carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses *(TheraTears)*

5521N **DEXTRAN-70 + HYPROMELLOSE**, dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses *(Bion Tears)***(Optometrical)**

8299T **DEXTRAN-70 + HYPROMELLOSE**, dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses *(Bion Tears)*

10040K **DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE**, docosahexaenoic acid with carbohydrate containing 200 mg docosahexaenoic acid oral liquid: powder for, 30 x 4g sachets *(docomega)*

5468T **DUTASTERIDE**, dutasteride 500 microgram capsule, 30 *(Avodart)*

5490Y **DUTASTERIDE + TAMSULOSIN**, dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram capsule: modified release, 30 *(Duodart 500ug/400ug)*

9113P **IMATINIB**, imatinib 100 mg tablet, 60 *(Glivec)*

9114Q **IMATINIB**, imatinib 400 mg tablet, 30 *(Glivec)*

3092R **MILK POWDER SYNTHETIC LOW CALCIUM**, milk powder synthetic low calcium oral liquid: powder for, 400 g *(Locasol)*

1166J **PHENOXYBENZAMINE**, phenoxybenzamine hydrochloride 10 mg capsule, 30 *(Amdipharm Mercury (Australia) Pty Limited)*

1862B **PHENOXYBENZAMINE**, phenoxybenzamine hydrochloride 10 mg capsule, 100 *(Dibenyline)*

9286R **PHENOXYBENZAMINE**, phenoxybenzamine hydrochloride 10 mg capsule, 100 *(Dibenzyline)*

5532E **POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**, polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses *(Systane)***(Optometrical)**

9170P **POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**, polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses *(Systane)*

2676W **PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES**, protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 400 g *(Alfaré)*

8259Q **PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES**, protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 450 g *(Aptamil Gold+ Pepti-Junior)*

1937Y **RANITIDINE**, ranitidine 150 mg tablet: effervescent, 30 *(Zantac)*

1978D **RANITIDINE**, ranitidine 150 mg tablet, 60 *(APO-Ranitidine, Ausran, Chem mart Ranitidine, GenRx Ranitidine, Rani 2, Ranitidine AN, Ranitidine GH, Ranitidine Sandoz, Ranoxyl, Terry White Chemists Ranitidine, Ulcaid, Zantac)*

10719E **RITUXIMAB**, rituximab 1.4 g/11.7 mL injection, 11.7 mL vial *(Mabthera SC)*

10742J **RITUXIMAB**, rituximab 1.4 g/11.7 mL injection, 11.7 mL vial *(Mabthera SC)*

2171G **SODIUM HYALURONATE**, sodium hyaluronate 0.2% (2 mg/mL) eye drops, 10 mL *(Hylo-Forte)***(Optometrical)**

2184Y **SODIUM HYALURONATE**, sodium hyaluronate 0.1% (1 mg/mL) eye drops, 10 mL *(Hylo-Fresh)***(Optometrical)**

5545W	**SOY LECITHIN + TOCOPHEROLS + VITAMIN A**, soy lecithin 1% + tocopherols 0.002% + vitamin A palmitate 0.025% eye spray, 100 actuations *(tearsagain)***(Optometrical)**
9448G	**SOY LECITHIN + TOCOPHEROLS + VITAMIN A**, soy lecithin 1% + tocopherols 0.002% + vitamin A palmitate 0.025% eye spray, 100 actuations *(tearsagain)*
10049X	**TRIGLYCERIDES MEDIUM CHAIN**, triglycerides medium chain oral liquid, 18 x 250 mL cartons *(betaquik)*
3128P	**TRIGLYCERIDES MEDIUM CHAIN**, triglycerides medium chain oil: oral, 500 mL *(MCT Oil)*
9327X	**TRIGLYCERIDES MEDIUM CHAIN**, triglycerides medium chain oral liquid, 250 mL bottle *(Liquigen)*
9383W	**TRIGLYCERIDES MEDIUM CHAIN FORMULA**, triglycerides medium chain formula oral liquid: powder for, 30 x 16 g sachets *(MCT Pro-Cal)*
10149E	**VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE**, vitamins, minerals and trace elements with carbohydrate oral liquid: powder for, 30 x 6 g sachets *(FruitiVits)*
9328Y	**VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE**, vitamins, minerals and trace elements with carbohydrate oral liquid: powder for, 200 g *(Paediatric Seravit)*
2870C	**WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE**, whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose oral liquid: powder for, 6 x 400 g cans *(Renastart)*
9382T	**WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE**, whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose oral liquid: powder for, 10 x 100 g sachets *(RenaStart)*
8587Y	**WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE**, whey protein formula supplemented with amino acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose oral liquid: powder for, 400 g *(Kindergen)*

Alteration – Restriction Level

		From	*To*
10036F	**ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE**, arachidonic acid and docosahexaenoic acid with carbohydrate containing 200 mg arachidonic acid and 100 mg docosahexaenoic acid oral liquid: powder for, 30 x 4 g sachets *(keyomega)*	authority-required	restricted
5502N	**CARBOMER-974**, carbomer-974 0.3% eye gel, 30 x 500 mg unit doses *(Poly Gel)* **(Optometrical)**	authority-required	streamlined
5504Q	**CARBOMER-980**, carbomer-980 0.2% eye drops, 30 x 0.6 mL unit doses *(Viscotears Gel PF)* **(Optometrical)**	authority-required	streamlined
5505R	**CARMELLOSE SODIUM**, carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses *(Celluvisc, Optifresh Plus)* **(Optometrical)**	authority-required	streamlined
5506T	**CARMELLOSE SODIUM**, carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses *(Cellufresh, Optifresh Tears)* **(Optometrical)**	authority-required	streamlined
5509Y	**CARMELLOSE SODIUM**, carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses *(TheraTears)* **(Optometrical)**	authority-required	streamlined
5510B	**CARMELLOSE SODIUM**, carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses *(TheraTears)* **(Optometrical)**	authority-required	streamlined
5521N	**DEXTRAN-70 + HYPROMELLOSE**, dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses *(Bion Tears)* **(Optometrical)**	authority-required	streamlined
10040K	**DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE**, docosahexaenoic acid with carbohydrate containing 200 mg docosahexaenoic acid oral liquid: powder for, 30 x 4g sachets *(docomega)*	authority-required	restricted
3092R	**MILK POWDER SYNTHETIC LOW CALCIUM**, milk powder synthetic low calcium oral liquid: powder for, 400 g *(Locasol)*	authority-required	restricted
1166J	**PHENOXYBENZAMINE**, phenoxybenzamine hydrochloride 10 mg capsule, 30 *(Amdipharm Mercury (Australia) Pty Limited)*	authority-required	restricted
1862B	**PHENOXYBENZAMINE**, phenoxybenzamine hydrochloride 10 mg capsule, 100 *(Dibenyline)*	authority-required	restricted

9286R	**PHENOXYBENZAMINE**, phenoxybenzamine hydrochloride 10 mg capsule, 100 *(Dibenzyline)*	authority-required	restricted
5532E	**POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**, polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses *(Systane)* **(Optometrical)**	authority-required	streamlined
2676W	**PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES**, protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 400 g *(Alfaré)*	authority-required	streamlined
8259Q	**PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES**, protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 450 g *(Aptamil Gold+ Pepti-Junior)*	authority-required	streamlined
2171G	**SODIUM HYALURONATE**, sodium hyaluronate 0.2% (2 mg/mL) eye drops, 10 mL *(Hylo-Forte)* **(Optometrical)**	authority-required	streamlined
2184Y	**SODIUM HYALURONATE**, sodium hyaluronate 0.1% (1 mg/mL) eye drops, 10 mL *(Hylo-Fresh)* **(Optometrical)**	authority-required	streamlined
5545W	**SOY LECITHIN + TOCOPHEROLS + VITAMIN A**, soy lecithin 1% + tocopherols 0.002% + vitamin A palmitate 0.025% eye spray, 100 actuations *(tearsagain)* **(Optometrical)**	authority-required	streamlined
10049X	**TRIGLYCERIDES MEDIUM CHAIN**, triglycerides medium chain oral liquid, 18 x 250 mL cartons *(betaquik)*	authority-required	streamlined
3128P	**TRIGLYCERIDES MEDIUM CHAIN**, triglycerides medium chain oil: oral, 500 mL *(MCT Oil)*	authority-required	streamlined
9327X	**TRIGLYCERIDES MEDIUM CHAIN**, triglycerides medium chain oral liquid, 250 mL bottle *(Liquigen)*	authority-required	streamlined
9383W	**TRIGLYCERIDES MEDIUM CHAIN FORMULA**, triglycerides medium chain formula oral liquid: powder for, 30 x 16 g sachets *(MCT Pro-Cal)*	authority-required	streamlined
10149E	**VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE**, vitamins, minerals and trace elements with carbohydrate oral liquid: powder for, 30 x 6 g sachets *(FruitiVits)*	authority-required	restricted
9328Y	**VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE**, vitamins, minerals and trace elements with carbohydrate oral liquid: powder for, 200 g *(Paediatric Seravit)*	authority-required	restricted
2870C	**WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE**, whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose oral liquid: powder for, 6 x 400 g cans *(Renastart)*	authority-required	streamlined
9382T	**WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE**, whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose oral liquid: powder for, 10 x 100 g sachets *(RenaStart)*	authority-required	streamlined
8587Y	**WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE**, whey protein formula supplemented with amino acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose oral liquid: powder for, 400 g *(Kindergen)*	authority-required	streamlined

Alteration – Manufacturer Code

		From	*To*
8361C	*Capecitabine MYX* – **CAPECITABINE**, capecitabine 150 mg tablet, 60	YN	OC
8362D	*Capecitabine MYX* – **CAPECITABINE**, capecitabine 500 mg tablet, 120	YN	OC
2479L	*Aridon APN 10* – **DONEPEZIL**, donepezil hydrochloride 10 mg tablet, 28	FM	RF
8496E	*Aridon APN 10* – **DONEPEZIL**, donepezil hydrochloride 10 mg tablet, 28	FM	RF
2532G	*Aridon APN 5* – **DONEPEZIL**, donepezil hydrochloride 5 mg tablet, 28	FM	RF

8495D	*Aridon APN 5* – **DONEPEZIL**, donepezil hydrochloride 5 mg tablet, 28	FM	RF
8600P	Nexole – **ESOMEPRAZOLE**, esomeprazole 20 mg tablet: enteric, 30	QA	RF
8886Q	*Nexole* – **ESOMEPRAZOLE**, esomeprazole 20 mg tablet: enteric, 30	QA	RF
3401B	*Nexole* – **ESOMEPRAZOLE**, esomeprazole 40 mg tablet: enteric, 30	QA	RF
8601Q	*Nexole* – **ESOMEPRAZOLE**, esomeprazole 40 mg tablet: enteric, 30	QA	RF
5043K	*Accu-Chek Aviva* – **GLUCOSE INDICATOR BLOOD**, glucose indicator blood diagnostic strip, 50	RD	RP
5053Y	*Accu-Chek Aviva* – **GLUCOSE INDICATOR BLOOD**, glucose indicator blood diagnostic strip, 50	RD	RP
8739Y	*Accu-Chek Go* – **GLUCOSE INDICATOR BLOOD**, glucose indicator blood diagnostic strip, 50	RD	RP
9274D	*Accu-Chek Go* – **GLUCOSE INDICATOR BLOOD**, glucose indicator blood diagnostic strip, 50	RD	RP
2979T	*Accu-Chek Performa* – **GLUCOSE INDICATOR BLOOD**, glucose indicator blood diagnostic strip, 100	RD	RP
8190C	*Accu-Chek Active* – **GLUCOSE INDICATOR BLOOD**, glucose indicator blood diagnostic strip, 100	RD	RP
9257F	*Accu-Chek Performa* – **GLUCOSE INDICATOR BLOOD**, glucose indicator blood diagnostic strip, 100	RD	RP
9273C	*Accu-Chek Active* – **GLUCOSE INDICATOR BLOOD**, glucose indicator blood diagnostic strip, 100	RD	RP
9300L	*Accu-Chek Mobile* – **GLUCOSE INDICATOR BLOOD**, glucose indicator blood diagnostic strip, 100	RD	RP
9301M	*Accu-Chek Mobile* – **GLUCOSE INDICATOR BLOOD**, glucose indicator blood diagnostic strip, 100	RD	RP
2588F	*Isordil Sublingual* – **ISOSORBIDE DINITRATE**, isosorbide dinitrate 5 mg tablet: sublingual, 100	QA	RW
1818Q	*Methotrexate MYX* – **METHOTREXATE**, METHOTREXATE Injection 50 mg in 2 mL, 1	YN	OC
5232J	*Zydol* – **TRAMADOL**, tramadol hydrochloride 50 mg capsule, 20 **(Dental)**	QA	RW
8455B	*Zydol* – **TRAMADOL**, tramadol hydrochloride 50 mg capsule, 20	QA	RW
8611F	*Zydol* – **TRAMADOL**, tramadol hydrochloride 50 mg capsule, 20	QA	RW
8523N	*Zydol SR 100* – **TRAMADOL**, tramadol hydrochloride 100 mg tablet: modified release, 20	QA	RW
8524P	*Zydol SR 150* – **TRAMADOL**, tramadol hydrochloride 150 mg tablet: modified release, 20	QA	RW
8525Q	*Zydol SR 200* – **TRAMADOL**, tramadol hydrochloride 200 mg tablet: modified release, 20	QA	RW

Advance Notices

1 July 2016

Deletion – Brand

9049G	*Cadatin 5/10, FZ* – **AMLODIPINE + ATORVASTATIN**, amlodipine 5 mg + atorvastatin 10 mg tablet, 30
9050H	*Cadatin 5/20, FZ* – **AMLODIPINE + ATORVASTATIN**, amlodipine 5 mg + atorvastatin 20 mg tablet, 30
9051J	*Cadatin 5/40, FZ* – **AMLODIPINE + ATORVASTATIN**, amlodipine 5 mg + atorvastatin 40 mg tablet, 30
9052K	*Cadatin 5/80, FZ* – **AMLODIPINE + ATORVASTATIN**, amlodipine 5 mg + atorvastatin 80 mg tablet, 30
9053L	*Cadatin 10/10, FZ* – **AMLODIPINE + ATORVASTATIN**, amlodipine 10 mg + atorvastatin 10 mg tablet, 30
9054M	*Cadatin 10/20, FZ* – **AMLODIPINE + ATORVASTATIN**, amlodipine 10 mg + atorvastatin 20 mg tablet, 30
9055N	*Cadatin 10/40, FZ* – **AMLODIPINE + ATORVASTATIN**, amlodipine 10 mg + atorvastatin 40 mg tablet, 30
9056P	*Cadatin 10/80, FZ* – **AMLODIPINE + ATORVASTATIN**, amlodipine 10 mg + atorvastatin 80 mg tablet, 30
1884E	*Amoxycillin-GA, FM* – **AMOXYCILLIN**, amoxycillin 250 mg capsule, 20

1889K *Amoxycillin-GA, FM* – **AMOXYCILLIN**, amoxycillin 500 mg capsule, 20

3300Q *Amoxycillin-GA, FM* – **AMOXYCILLIN**, amoxycillin 500 mg capsule, 20 **(Dental)**

3301R *Amoxycillin-GA, FM* – **AMOXYCILLIN**, amoxycillin 250 mg capsule, 20 **(Dental)**

1891M *GA-Amclav 500/125, FM* – **AMOXYCILLIN + CLAVULANIC ACID**, amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10

1892N *GA-Amclav 125/31.25, FM* – **AMOXYCILLIN + CLAVULANIC ACID**, amoxycillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL oral liquid: powder for, 75 mL

5006L *GA-Amclav Forte 875/125, FM* – **AMOXYCILLIN + CLAVULANIC ACID**, amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10 **(Dental)**

5008N *GA-Amclav 500/125, FM* – **AMOXYCILLIN + CLAVULANIC ACID**, amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10 **(Dental)**

5009P *GA-Amclav 125/31.25, FM* – **AMOXYCILLIN + CLAVULANIC ACID**, amoxycillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL oral liquid: powder for, 75 mL **(Dental)**

5011R *GA-Amclav Forte 400/57, FM* – **AMOXYCILLIN + CLAVULANIC ACID**, amoxycillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL oral liquid: powder for, 60 mL **(Dental)**

8254K *GA-Amclav Forte 875/125, FM* – **AMOXYCILLIN + CLAVULANIC ACID**, amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10

8319W *GA-Amclav Forte 400/57, FM* – **AMOXYCILLIN + CLAVULANIC ACID**, amoxycillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL oral liquid: powder for, 60 mL

1473M *Fluconazole Hexal, HX* – **FLUCONAZOLE**, fluconazole 100 mg/50 mL injection, 50 mL vial

1474N *Fluconazole Hexal, HX* – **FLUCONAZOLE**, fluconazole 200 mg/100 mL injection, 100 mL vial

1 August 2016

Deletion – Brand

3036T *Protos 2 g, SE* – **STRONTIUM,** strontium ranelate 2 g granules, 28 x 2 g sachets

Delisting of strontium will be recommended for determination to take effect 1 August 2016 in accordance with Pharmaceutical Benefits Advisory Committee advice to the Minister. There are alternative therapies available.

1 September 2016

Deletion – Brand

8423H *Dilaudid-HP, MF* – **HYDROMORPHONE**, hydromorphone hydrochloride 500 mg/50 mL injection, 50 mL vial

Palliative Care

Deletions

Deletion – Item

5386L **BENZYDAMINE**, benzydamine hydrochloride 0.15% mouthwash, 500 mL *(Difflam)*

5307H **BISACODYL**, bisacodyl 10 mg suppository, 10 *(Dulcolax, Petrus Bisacodyl Suppositories)*

5308J **BISACODYL**, bisacodyl 10 mg suppository, 12 *(Petrus Bisacodyl Suppositories)*

5306G **BISACODYL**, bisacodyl 10 mg/5 mL enema, 25 x 5 mL *(Bisalax)*

5305F **BISACODYL**, bisacodyl 5 mg tablet: enteric, 200 *(Lax-Tab)*

5342E **CLONAZEPAM**, clonazepam 2.5 mg/mL oral liquid, 10 mL *(Rivotril)*

5340C **CLONAZEPAM**, clonazepam 500 microgram tablet, 100 *(Paxam 0.5, Rivotril)*

5341D **CLONAZEPAM**, clonazepam 2 mg tablet, 100 *(Paxam 2, Rivotril)*

5357Y **DIAZEPAM**, diazepam 2 mg tablet, 50 *(APO-Diazepam, Antenex 2, Ranzepam, Valpam 2)*

5358B **DIAZEPAM**, diazepam 5 mg tablet, 50 *(APO-Diazepam, Antenex 5, Ranzepam, Valium, Valpam 5)*

5366K **DICLOFENAC**, diclofenac sodium 100 mg suppository, 20 *(Voltaren 100)*

5364H **DICLOFENAC**, diclofenac sodium 25 mg tablet: enteric, 50 *(APO-Diclofenac, Chem mart Diclofenac, Clonac 25, Diclofenac AN, Diclofenac Sandoz, Diclofenac-GA, Fenac 25, Terry White Chemists Diclofenac, Voltaren 25)*

5365J **DICLOFENAC**, diclofenac sodium 50 mg tablet: enteric, 50 *(APO-Diclofenac, Chem mart Diclofenac, Clonac 50, Diclofenac AN, Diclofenac Sandoz, Diclofenac-GA, Fenac, Terry White Chemists Diclofenac, Voltaren 50)*

5318X **HYOSCINE BUTYLBROMIDE**, hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules *(Buscopan)*

5370P **IBUPROFEN**, ibuprofen 400 mg tablet, 30 *(Brufen)*

5379D **INDOMETHACIN**, indomethacin 25 mg capsule, 50 *(Arthrexin, Indocid)*

5380E **INDOMETHACIN**, indomethacin 100 mg suppository, 20 *(Indocid)*

5427P **MACROGOL-3350**, macrogol-3350 1 g/g oral liquid: powder for, 510 g *(OsmoLax)*

2353W **MACROGOL-3350**, macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets *(Herron ClearLax)*

10112F **MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE**, macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL *(Movicol Liquid)*

5390Q **MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE**, macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets *(APO-MACROGOL plus ELECTROLYTES, Chemists' Own Macrogol with Electrolytes, LaxaCon, Macrovic, Molaxole, Movicol, lax-sachets)*

5395Y **MORPHINE**, morphine sulfate 10 mg tablet, 20 *(Sevredol)*

5396B **MORPHINE**, morphine sulfate 20 mg tablet, 20 *(Sevredol)*

5392T **MORPHINE**, morphine sulfate 200 mg tablet: modified release, 28 *(MS Contin)*

5398D **NAPROXEN**, naproxen 125 mg/5 mL oral liquid, 474 mL *(Phebra Naproxen Suspension)*

5349M **NAPROXEN**, naproxen 250 mg tablet, 50 *(Inza 250, Naprosyn)*

5350N **NAPROXEN**, naproxen 500 mg tablet, 50 *(Inza 500, Naprosyn)*

5354T **NAPROXEN**, naproxen sodium 550 mg tablet, 50 *(Anaprox 550, Crysanal)*

5351P **NAPROXEN**, naproxen 750 mg tablet: modified release, 28 *(Naprosyn SR750, Proxen SR 750)*

5352Q **NAPROXEN**, naproxen 1 g tablet: modified release, 28 *(Naprosyn SR1000, Proxen SR 1000)*

5360D **NITRAZEPAM**, nitrazepam 5 mg tablet, 25 *(Alodorm, Mogadon)*

5373T **OXAZEPAM**, oxazepam 15 mg tablet, 25 *(Alepam 15, Serepax)*

5374W **OXAZEPAM**, oxazepam 30 mg tablet, 25 *(APO-Oxazepam, Alepam 30, Murelax, Serepax)*

5320B **PARACETAMOL**, paracetamol 500 mg suppository, 24 *(Panadol)*

5344G **PARACETAMOL**, paracetamol 665 mg tablet: modified release, 96 *(Osteomol 665 Paracetamol)*

5324F **RHAMNUS FRANGULA + STERCULIA**, rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g *(Normacol Plus)*

5332P **SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM**, sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL *(Micolette, Microlax)*

5376Y **TEMAZEPAM**, temazepam 10 mg tablet, 25 *(APO-Temazepam, Normison, Temaze, Temtabs)*

Alterations

Alteration – Restriction

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

5385K **BENZYDAMINE**, benzydamine hydrochloride 0.15% mouthwash, 500 mL *(Difflam)*

5301B **BISACODYL**, bisacodyl 5 mg tablet: enteric, 200 *(Lax-Tab)*

5302C **BISACODYL**, bisacodyl 10 mg/5 mL enema, 25 x 5 mL *(Bisalax)*

5303D **BISACODYL**, bisacodyl 10 mg suppository, 10 *(Dulcolax, Petrus Bisacodyl Suppositories)*

5304E **BISACODYL**, bisacodyl 10 mg suppository, 12 *(Petrus Bisacodyl Suppositories)*

5337X **CLONAZEPAM**, clonazepam 500 microgram tablet, 100 *(Paxam 0.5, Rivotril)*

5338Y **CLONAZEPAM**, clonazepam 2 mg tablet, 100 *(Paxam 2, Rivotril)*

5339B **CLONAZEPAM**, clonazepam 2.5 mg/mL oral liquid, 10 mL *(Rivotril)*

5355W **DIAZEPAM**, diazepam 2 mg tablet, 50 *(APO-Diazepam, Antenex 2, Ranzepam, Valpam 2)*

5356X **DIAZEPAM**, diazepam 5 mg tablet, 50 *(APO-Diazepam, Antenex 5, Ranzepam, Valium, Valpam 5)*

5361E **DICLOFENAC**, diclofenac sodium 25 mg tablet: enteric, 50 *(APO-Diclofenac, Chem mart Diclofenac, Clonac 25, Diclofenac AN, Diclofenac Sandoz, Diclofenac-GA, Fenac 25, Terry White Chemists Diclofenac, Voltaren 25)*

5362F **DICLOFENAC**, diclofenac sodium 50 mg tablet: enteric, 50 *(APO-Diclofenac, Chem mart Diclofenac, Clonac 50, Diclofenac AN, Diclofenac Sandoz, Diclofenac-GA, Fenac, Terry White Chemists Diclofenac, Voltaren 50)*

5363G **DICLOFENAC**, diclofenac sodium 100 mg suppository, 20 *(Voltaren 100)*

5317W **HYOSCINE BUTYLBROMIDE**, hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules *(Buscopan)*

5368M **IBUPROFEN**, ibuprofen 400 mg tablet, 30 *(Brufen)*

5377B **INDOMETHACIN**, indomethacin 25 mg capsule, 50 *(Arthrexin, Indocid)*

5378C **INDOMETHACIN**, indomethacin 100 mg suppository, 20 *(Indocid)*

2351R **MACROGOL-3350**, macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets *(Herron ClearLax)*

5426N **MACROGOL-3350**, macrogol-3350 1 g/g oral liquid: powder for, 510 g *(OsmoLax)*

10127B **MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE**, macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL *(Movicol Liquid)*

5389P **MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE**, macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets *(APO-MACROGOL plus ELECTROLYTES, Chemists' Own Macrogol with Electrolytes, LaxaCon, Macrovic, Molaxole, Movicol, lax-sachets)*

5423K **METHYLNALTREXONE**, methylnaltrexone bromide 12 mg/0.6 mL injection, 0.6 mL vial *(Relistor)*

5424L **METHYLNALTREXONE**, METHYLNALTREXONE Solution for injection containing methylnaltrexone bromide 12 mg in 0.6 mL, 7 *(Relistor)*

5391R **MORPHINE**, morphine sulfate 200 mg tablet: modified release, 28 *(MS Contin)*

5393W **MORPHINE**, morphine sulfate 10 mg tablet, 20 *(Sevredol)*

5394X **MORPHINE**, morphine sulfate 20 mg tablet, 20 *(Sevredol)*

5345H **NAPROXEN**, naproxen 250 mg tablet, 50 *(Inza 250, Naprosyn)*

5346J **NAPROXEN**, naproxen 500 mg tablet, 50 *(Inza 500, Naprosyn)*

5347K **NAPROXEN**, naproxen 750 mg tablet: modified release, 28 *(Naprosyn SR750, Proxen SR 750)*

5348L **NAPROXEN**, naproxen 1 g tablet: modified release, 28 *(Naprosyn SR1000, Proxen SR 1000)*

5353R **NAPROXEN**, naproxen sodium 550 mg tablet, 50 *(Anaprox 550, Crysanal)*

5397C **NAPROXEN**, naproxen 125 mg/5 mL oral liquid, 474 mL *(Phebra Naproxen Suspension)*

5359C **NITRAZEPAM**, nitrazepam 5 mg tablet, 25 *(Alodorm, Mogadon)*

5371Q **OXAZEPAM**, oxazepam 15 mg tablet, 25 *(Alepam 15, Serepax)*

5372R **OXAZEPAM**, oxazepam 30 mg tablet, 25 *(APO-Oxazepam, Alepam 30, Murelax, Serepax)*

5319Y **PARACETAMOL**, paracetamol 500 mg suppository, 24 *(Panadol)*

5343F **PARACETAMOL**, paracetamol 665 mg tablet: modified release, 96 *(Osteomol 665 Paracetamol)*

5322D **RHAMNUS FRANGULA + STERCULIA**, rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g *(Normacol Plus)*

5331N **SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM**, sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL *(Micolette, Microlax)*

5375X **TEMAZEPAM**, temazepam 10 mg tablet, 25 *(APO-Temazepam, Normison, Temaze, Temtabs)*

Alteration – Restriction Level

		From	*To*
5301B	**BISACODYL**, bisacodyl 5 mg tablet: enteric, 200 *(Lax-Tab)*	streamlined	restricted
5302C	**BISACODYL**, bisacodyl 10 mg/5 mL enema, 25 x 5 mL *(Bisalax)*	streamlined	restricted

5303D	**BISACODYL**, bisacodyl 10 mg suppository, 10 *(Dulcolax, Petrus Bisacodyl Suppositories)*	streamlined	restricted
5304E	**BISACODYL**, bisacodyl 10 mg suppository, 12 *(Petrus Bisacodyl Suppositories)*	streamlined	restricted
5361E	**DICLOFENAC**, diclofenac sodium 25 mg tablet: enteric, 50 *(APO-Diclofenac, Chem mart Diclofenac, Clonac 25, Diclofenac AN, Diclofenac Sandoz, Diclofenac-GA, Fenac 25, Terry White Chemists Diclofenac, Voltaren 25)*	streamlined	restricted
5362F	**DICLOFENAC**, diclofenac sodium 50 mg tablet: enteric, 50 *(APO-Diclofenac, Chem mart Diclofenac, Clonac 50, Diclofenac AN, Diclofenac Sandoz, Diclofenac-GA, Fenac, Terry White Chemists Diclofenac, Voltaren 50)*	streamlined	restricted
5363G	**DICLOFENAC**, diclofenac sodium 100 mg suppository, 20 *(Voltaren 100)*	authority-required	restricted
5368M	**IBUPROFEN**, ibuprofen 400 mg tablet, 30 *(Brufen)*	authority-required	restricted
5377B	**INDOMETHACIN**, indomethacin 25 mg capsule, 50 *(Arthrexin, Indocid)*	streamlined	restricted
5378C	**INDOMETHACIN**, indomethacin 100 mg suppository, 20 *(Indocid)*	authority-required	restricted
5423K	**METHYLNALTREXONE**, methylnaltrexone bromide 12 mg/0.6 mL injection, 0.6 mL vial *(Relistor)*	authority-required	streamlined
5424L	**METHYLNALTREXONE**, METHYLNALTREXONE Solution for injection containing methylnaltrexone bromide 12 mg in 0.6 mL, 7 *(Relistor)*	authority-required	streamlined
5345H	**NAPROXEN**, naproxen 250 mg tablet, 50 *(Inza 250, Naprosyn)*	streamlined	restricted
5346J	**NAPROXEN**, naproxen 500 mg tablet, 50 *(Inza 500, Naprosyn)*	streamlined	restricted
5347K	**NAPROXEN**, naproxen 750 mg tablet: modified release, 28 *(Naprosyn SR750, Proxen SR 750)*	streamlined	restricted
5348L	**NAPROXEN**, naproxen 1 g tablet: modified release, 28 *(Naprosyn SR1000, Proxen SR 1000)*	streamlined	restricted
5353R	**NAPROXEN**, naproxen sodium 550 mg tablet, 50 *(Anaprox 550, Crysanal)*	streamlined	restricted
5397C	**NAPROXEN**, naproxen 125 mg/5 mL oral liquid, 474 mL *(Phebra Naproxen Suspension)*	streamlined	restricted
5319Y	**PARACETAMOL**, paracetamol 500 mg suppository, 24 *(Panadol)*	streamlined	restricted
5343F	**PARACETAMOL**, paracetamol 665 mg tablet: modified release, 96 *(Osteomol 665 Paracetamol)*	streamlined	restricted
5322D	**RHAMNUS FRANGULA + STERCULIA**, rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g *(Normacol Plus)*	streamlined	restricted
5331N	**SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM**, sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL *(Micolette, Microlax)*	streamlined	restricted

Alteration – Maximum Quantity

		From	*To*
5423K	**METHYLNALTREXONE**, methylnaltrexone bromide 12 mg/0.6 mL injection, 0.6 mL vial *(Relistor)*	3	7

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Brand

6100C *Azadine, RZ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

6138C *Azadine, RZ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

Addition – Equivalence Indicator

6100C *Vidaza, CJ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

6138C *Vidaza, CJ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

Alterations

Alteration – Restriction

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

6100C **AZACITIDINE**, azacitidine 100 mg injection, 1 vial *(Azadine, Vidaza)*

6138C **AZACITIDINE**, azacitidine 100 mg injection, 1 vial *(Azadine, Vidaza)*

9744W **LEVODOPA + CARBIDOPA ANHYDROUS**, levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL *(Duodopa)*

10110D **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 1 x 0.5 mL syringe *(Xolair)*

10122R **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 x 1 mL syringe *(Xolair)*

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Brand

9597D *Azadine, RZ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

9598E *Azadine, RZ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

Addition – Equivalence Indicator

9597D *Vidaza, CJ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

9598E *Vidaza, CJ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial

Alterations

Alteration – Restriction

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

9597D **AZACITIDINE**, azacitidine 100 mg injection, 1 vial *(Azadine, Vidaza)*

9598E **AZACITIDINE**, azacitidine 100 mg injection, 1 vial *(Azadine, Vidaza)*

9743T **LEVODOPA + CARBIDOPA ANHYDROUS**, levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL *(Duodopa)*

10109C **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 x 1 mL syringe *(Xolair)*

10118M **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 1 x 0.5 mL syringe *(Xolair)*

Highly Specialised Drugs Program (Community Access)

Advance Notices

1 August 2016

Deletion – Brand

10372X *Sebivo, NV* – **TELBIVUDINE**, telbivudine 600 mg tablet, 28

Repatriation Pharmaceutical Benefits

Additions

Addition – Item

10586E **GLYCEROL**, glycerol 700 mg suppository, 12 *(Petrus Pharmaceuticals Pty Ltd)*

10596Q **GLYCEROL**, glycerol 1.4 g suppository, 12 *(Petrus Pharmaceuticals Pty Ltd)*

4246L **GLYCEROL**, glycerol 2.8 g suppository, 12 *(Petrus Pharmaceuticals Pty Ltd)*

About the Schedule

The Schedule of Pharmaceutical Benefits lists all of the ready-prepared items subsidised under the Pharmaceutical Benefits Scheme (PBS).

The Schedule is published and is effective on the first day of each month.

For detailed information about the prescribing and supply of pharmaceutical benefits go to www.pbs.gov.au

For information about the operational aspects of the PBS, such as, PBS claiming, authority applications and stationery supplies contact the Department of Human Services at www.humanservices.gov.au

The Repatriation Schedule of Pharmaceutical Benefits provides information about pharmaceutical benefits available under the Repatriation Pharmaceutical Benefits Scheme (RPBS). These may only be prescribed to Department of Veterans' Affairs (DVA) beneficiaries holding a valid repatriation health card. Queries relating to the RPBS can be made to the DVA or go to www.dva.gov.au

Symbols and Abbreviations Used in the Schedule

*	An asterisk in the dispensed price column indicates that the manufacturer's pack does not coincide with the maximum quantity
‡	A double dagger in the maximum quantity column indicates where the maximum quantity has been determined to match the manufacturer's pack. These packs cannot be broken and the maximum quantity should be supplied and claimed
#	A gauge in the dispensed price column indicates that the product is not preconstituted and that the dispensed price therefore included a dispensing fee and where appropriate, an amount for purified water
a or b	Located immediately before brand names of an item indicates that the brands are equivalent for the purposes of substitution. These brands may be interchanged without differences in clinical effect
B	located immediately before an amount in the premium column indicates a brand premium which applies to that particular brand of the item
T	located immediately before an amount in the premium column indicates a therapeutic group premium which applies to that particular item.
S	located immediately before an amount in the premium column indicates a special patient contribution which applies to that particular item.
DPMQ $	Dispensed price for maximum quantity
MRVSN $	Maximum recordable value for safety net
NP	Indicates that the item can be prescribed by an authorised nurse practitioner
MW	Indicates that the item can be prescribed by an authorised midwife
OP	Indicates that the item can be prescribed by an authorised optometrist
DP	Indicates that the item can be prescribed by an authorised dental practitioner

Restricted Benefits

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

Restricted benefits - above an item indicates where an item can only be prescribed for specific therapeutic uses.

Authority required benefits – above an item indicates that a prescriber must seek approval from Department of Human Services or the Department of Veterans' Affairs. The prescriber must declare the specific conditions and circumstances that justify the use of these medicines. This is usually done by phone or in writing

Authority required (STREAMLINED) – authority can be sought electronically.

Guidelines and General Statements

General Statement for Lipid-Lowering Drugs

Use the following criteria to determine patient eligibility for subsidisation under the PBS for lipid modifying agents.

By writing a PBS prescription, the prescriber is certifying the patient satisfies the qualifying criteria set out below and the use is in accordance with the registered indications which differ between agents in this class - refer to the current Product Information for details. Note also that patients already established on a particular lipid-lowering drug, where use satisfies the PBS qualifying criteria, but is outside the registered indications for that drug, are not required to switch to another drug in the class to retain PBS eligibility.

Patients in very high risk categories (see below) may commence drug therapy with statins or fibrates immediately (ie simultaneously with an appropriate diet). For all other patients, dietary therapy should be trialled prior to initiation of drug therapy.

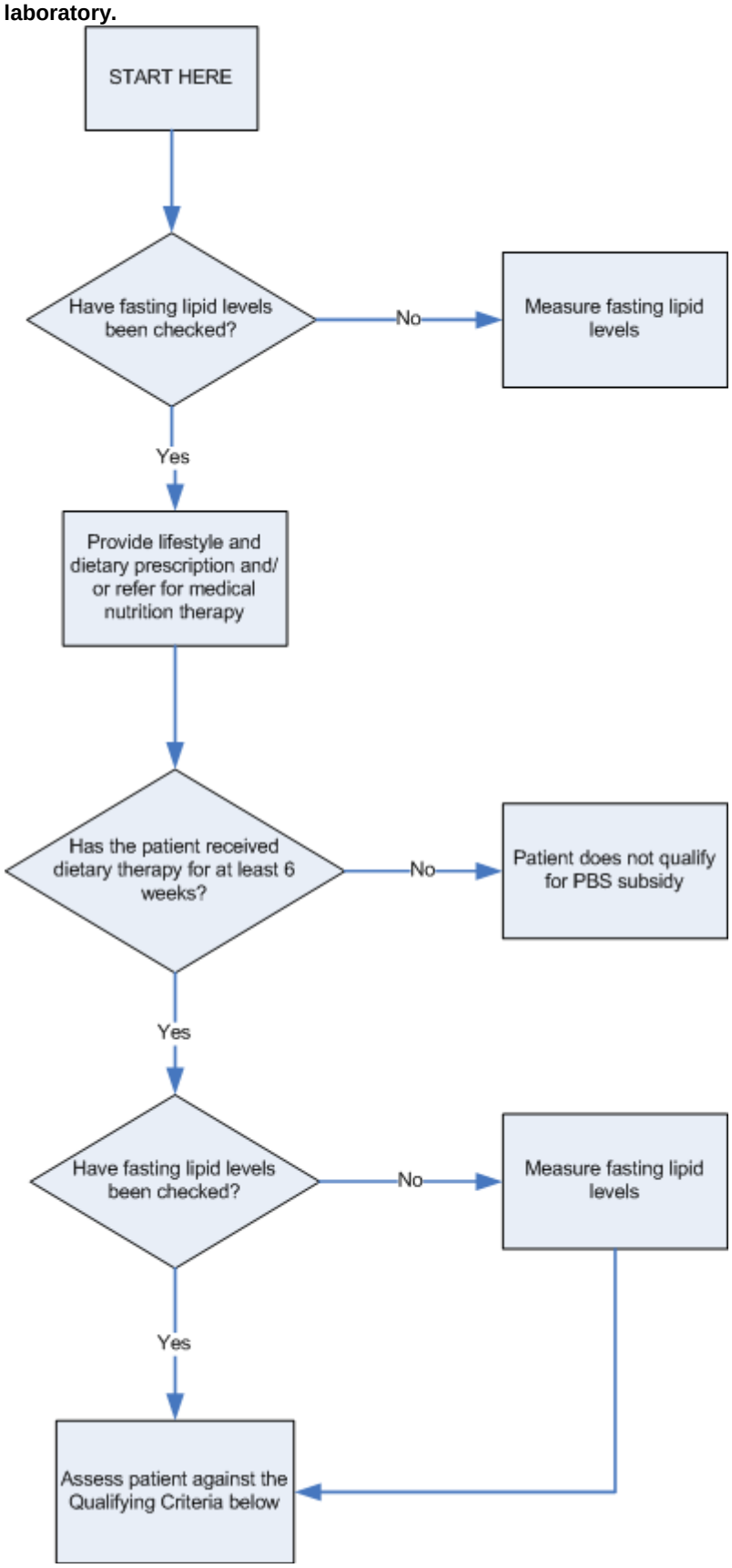
Dietary therapy should be continued concurrently with pharmacological therapy and should be reviewed on at least an annual basis.
Patients identified as being in one of the following very high risk categories may commence drug therapy with statins or fibrates at any cholesterol level:

- coronary heart disease which has become symptomatic
- cerebrovascular disease which has become symptomatic
- peripheral vascular disease which has become symptomatic
- diabetes mellitus with microalbuminuria (defined as urinary albumin excretion rate of >20mcg/min or urinary albumin to creatinine ratio of > 2.5 for males, > 3.5 for females)
- diabetes mellitus in Aboriginal or Torres Strait Islander patients
- diabetes mellitus in patients aged 60 years or more
- family history of coronary heart disease which has become symptomatic before the age of 55 years in two or more first degree relatives
- family history of coronary heart disease which has become symptomatic before the age of 45 years in one or more first degree relatives

POST-DIETARY QUALIFYING CRITERIA
Dietary therapy should be continued concurrently with pharmacological therapy and should be reviewed on at least an annual basis.

PATIENT CATEGORY	LIPID LEVELS FOR PBS SUBSIDY
Patients with diabetes mellitus not otherwise included	total cholesterol > 5.5 mmol/L
Aboriginal or Torres Strait Islander patients Patients with hypertension	total cholesterol > 6.5 mmol/L; **or** total cholesterol > 5.5 mmol/L; **and** HDL cholesterol < 1 mmol/L
Patients with HDL cholesterol < 1 mmol/L	total cholesterol > 6.5 mmol/L
Patients with familial hypercholesterolaemia identified by: • DNA mutation; or • tendon xanthomas in the patient or their first or second degree relative Patients with: • family history of coronary heart disease which has become symptomatic before the age of 60 years in one or more first degree relatives; or • family history of coronary heart disease which has become symptomatic before the age of 50 years in one or more second degree relatives	If aged 18 years or less at treatment initiation: LDL cholesterol > 4 mmol/L If aged more than 18 years at treatment initiation: LDL cholesterol > 5 mmol/L; **or** total cholesterol > 6.5 mmol/L; **or** total cholesterol > 5.5 mmol/L; **and** HDL cholesterol < 1 mmol/L
Patients not eligible under the above: • men aged 35 to 75 years • post-menopausal women aged up to 75 years	total cholesterol > 7.5 mmol/L; **or** triglyceride > 4 mmol/L
Patients not otherwise included	total cholesterol > 9 mmol/L; **or** triglyceride > 8 mmol/L

If your patient is not identified as being in any of the above very high risk categories, then use the flow-chart and table below to determine whether your patient satisfies the following criteria for subsidisation under the PBS. Document how the patient meets each of these steps in the patient record. Lipid levels must be measured at an accredited laboratory.



General Statement for Drugs for the Treatment of Hepatitis C

Use the following criteria to determine patient eligibility for subsidisation under the PBS for hepatitis C treating agents.
By writing a PBS prescription, the prescriber is certifying the patient satisfies the qualifying criteria set out below and the use in accordance with the registered indications which differ between agents in this class – refer to the current Product Information for details.

Population criteria:
Patient must be aged 18 years or older.

Treatment criteria:
Must be treated by a gastroenterologist, hepatologist or infectious diseases physician experienced in the treatment of chronic hepatitis C infection; or in consultation with a gastroenterologist, hepatologist or infectious diseases physician experienced in the treatment of chronic hepatitis C infection.

The following information must be provided at the time of application:
a) the hepatitis C virus genotype; and
b) the patient's cirrhotic status (non-cirrhotic or cirrhotic)
The following information must be documented in the patient's medical records:
a) evidence of chronic hepatitis C infection (repeatedly antibody to hepatitis C virus (anti-HCV) positive and hepatitis C virus ribonucleic acid (HCV RNA) positive); and
b) evidence of the hepatitis C virus genotype
The following matrices identify the regimens which are available for PBS prescription for eligible patients, based on the hepatitis C virus genotype and treatment history.

HEPATITIS C - NON-CIRRHOTIC PATIENTS

	TREATMENT NAIVE	**TREATMENT EXPERIENCED**
Genotype 1	LEDIPASVIR + SOFOSBUVIR [8 or 12 weeks] [1] OR DACLATASVIR and SOFOSBUVIR [12 weeks] OR SOFOSBUVIR and PEG-IFN (&) RBV [12 weeks] OR PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR [12 weeks] [2] OR PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV [12 weeks] [3]	LEDIPASVIR + SOFOSBUVIR [12 weeks] [4] OR DACLATASVIR and SOFOSBUVIR [12 or 24 weeks] [5] OR SOFOSBUVIR and PEG-IFN (&) RBV [12 weeks] OR PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR [12 weeks] [2] OR PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV [12 weeks] [3]
Genotype 2	SOFOSBUVIR and RBV [12 weeks]	SOFOSBUVIR and RBV [12 weeks]
Genotype 3	DACLATASVIR and SOFOSBUVIR [12 weeks] OR SOFOSBUVIR and RBV [24 weeks] OR SOFOSBUVIR and PEG-IFN (&) RBV [12 weeks]	DACLATASVIR and SOFOSBUVIR [12 weeks] [6] OR SOFOSBUVIR and RBV [24 weeks] OR SOFOSBUVIR and PEG-IFN (&) RBV [12 weeks]
Genotype 4, 5, 6	SOFOSBUVIR and PEG-IFN (&) RBV [12 weeks]	SOFOSBUVIR and PEG-IFN (&) RBV [12 weeks]

KEY PEG-IFN/RBV – peginterferon alfa-2a (&) ribavirin RBV – ribavirin

[1] [LEDIPASVIR + SOFOSBUVIR] for treatment-naive, non-cirrhotic patients:
- consider treatment for 8 weeks where pre-treatment HCV RNA is less than 6 million IU/mL;
- otherwise treatment for 12 weeks where pre-treatment HCV RNA is 6 million IU/mL or greater.

[2] [PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR] for treatment-naïve and treatment experienced, non-cirrhotic patients, treatment for 12 weeks in patients with genotype 1b HCV.

[3] [PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV] for treatment-naïve and treatment experienced, non-cirrhotic patients, treatment for 12 weeks in patients with genotype 1a HCV.

[4] A 12 weeks treatment regimen for [LEDIPASVIR + SOFOSBUVIR] for treatment-experienced, non-cirrhotic patients who have failed prior treatment with either:
- PEG-IFN alfa (&) RBV; or
- a HCV protease inhibitor + PEG-IFN alfa (&) RBV.

[5] [DACLATASVIR and SOFOSBUVIR] for treatment-experienced, non-cirrhotic patients:
- consider treatment for 12 weeks in patients who have failed PEG-IFN alfa (&) RBV; or
- consider treatment for 24 weeks in patients who have failed a protease inhibitor + PEG-IFN (&) RBV.

[6] [DACLATASVIR and SOFOSBUVIR] for treatment-experienced, non-cirrhotic patients, treatment for 12 weeks in patients:
- who have failed SOFOSBUVIR and RBV; or
- who have failed PEG IFN alfa (&) RBV.

HEPATITIS C – CIRRHOTIC PATIENTS

	TREATMENT NAIVE	TREATMENT EXPERIENCED
Genotype 1	LEDIPASVIR + SOFOSBUVIR [12 weeks] OR DACLATASVIR and SOFOSBUVIR and RBV [12 weeks] OR DACLATASVIR and SOFOSBUVIR [24 weeks] OR SOFOSBUVIR and PEG-IFN (&) RBV [12 weeks] OR PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV [12 weeks]	LEDIPASVIR + SOFOSBUVIR [24 weeks] [7] OR DACLATASVIR and SOFOSBUVIR [24 weeks] [8] OR DACLATASVIR and SOFOSBUVIR and RBV [12 weeks] [9] OR SOFOSBUVIR and PEG-IFN (&) RBV [12 weeks] OR PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV [12 or 24 weeks] [10]
Genotype 2	SOFOSBUVIR and RBV [12 weeks]	SOFOSBUVIR and RBV [12 weeks]
Genotype 3	SOFOSBUVIR and RBV [24 weeks] OR DACLATASVIR and SOFOSBUVIR [24 weeks] OR SOFOSBUVIR and PEG-IFN (&) RBV [12 weeks]	DACLATASVIR and SOFOSBUVIR [24 weeks] [11] OR SOFOSBUVIR and RBV [24 weeks] OR SOFOSBUVIR and PEG-IFN (&) RBV [12 weeks]
Genotype 4, 5, 6	SOFOSBUVIR and PEG-IFN (&) RBV [12 weeks]	SOFOSBUVIR and PEG-IFN (&) RBV [12 weeks]

KEY PEG-IFN (&) RBV- peginterferon alfa-2a (&) ribavirin RBV – ribavirin

[7] A 24 weeks treatment regimen for [LEDIPASVIR + SOFOSBUVIR] for treatment-experienced, cirrhotic patients who have failed prior treatment with either:
- PEG-IFN alfa (&) RBV; or
- a HCV protease inhibitor + PEG-IFN alfa (&) RBV.

[8] A 24 weeks treatment regimen for [DACLATASVIR and SOFOSBUVIR] for treatment-experienced, cirrhotic patients who have failed prior treatment with either:
- PEG-IFN alfa (&) RBV; or
- a HCV protease inhibitor and PEG-IFN (&) RBV.

[9] [DACLATASVIR and SOFOSBUVIR and RBV] for treatment-experienced cirrhotic patients:
- consider treatment for 12 weeks in patients who have failed PEG-IFN alfa (&) RBV.

[10] [PARITAPREVIR + RITONAVIR + OMBITASVIR (&) DASABUVIR (&) RBV] for treatment-experienced, cirrhotic patients:
- consider treatment for 12 weeks in patients with genotype 1a HCV (except prior null responders to PEG-IFN (&) RBV) and genotype 1b HCV; or
- consider treatment for 24 weeks in patients with genotype 1a HCV who have had a previous null response to PEG-IFN (&) RBV.

[11] [DACLATASVIR and SOFOSBUVIR] for treatment-experienced cirrhotic patients, treatment for 24 weeks in patients :
- who have failed SOFOSBUVIR and RBV; or
- who have failed PEG IFN alfa (&) RBV.

Pharmaceutical Benefits Schedules

Prescriber Bag

▪ ADRENALINE

adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules

3451P	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
NP	1	21.91	Link Medical Products Pty Ltd [LM]

▪ ATROPINE SULFATE

ATROPINE Injection 600 micrograms in 1 mL, 10

3453R	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
NP	1	22.09	Pfizer Australia Pty Ltd [PF]

▪ BENZTROPINE

benztropine mesylate 2 mg/2 mL injection, 10 x 2 mL vials

10016E	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
NP	1	262.61	Benztropine Omega [FK]

OR

benztropine mesylate 2 mg/2 mL injection, 5 x 2 mL ampoules

3457Y	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
NP	1	94.34	Cogentin [FK]

▪ BENZYLPENICILLIN

benzylpenicillin 600 mg injection, 1 vial

3486L	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
NP	5	*34.33	BenPen [CS]

OR

▪ PROCAINE PENICILLIN

procaine penicillin 1.5 g/3.4 mL injection, 5 x 3.4 mL syringes

3485K	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
NP	1	84.51	Cilicaine [QA]

▪ BENZYLPENICILLIN

benzylpenicillin 3 g injection, 1 vial

3487M	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
NP	1	18.68	BenPen [CS]

▪ CHLORPROMAZINE

chlorpromazine hydrochloride 50 mg/2 mL injection, 10 x 2 mL ampoules

3455W	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
NP	1	22.03	Largactil [SW]

OR

▪ HALOPERIDOL

haloperidol 5 mg/mL injection, 10 x 1 mL ampoules

3456X	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
NP	1	23.53	Serenace [QA]

▪ CLONAZEPAM

clonazepam 2.5 mg/mL oral liquid, 10 mL

3478C	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
NP	‡1	14.17	Rivotril [RO]

▪ DEXAMETHASONE SODIUM PHOSPHATE

DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 4 mg dexamethasone phosphate in 1 mL, 5

3472R	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	15.69	[a] Dexamethasone Mylan [AF]	[a] Hospira Pty Limited [HH]

OR

▪ HYDROCORTISONE SODIUM SUCCINATE

hydrocortisone (as sodium succinate) 100 mg injection [1 vial] (&) inert substance diluent [2 mL vial], 1 pack

3470P	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
NP	2	*20.23	Solu-Cortef [PF]

OR

hydrocortisone (as sodium succinate) 250 mg injection [1 vial] (&) inert substance diluent [2 mL vial], 1 pack

3471Q	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
NP	1	19.18	Solu-Cortef [PF]

▪ DIAZEPAM

diazepam 10 mg/2 mL injection, 5 x 2 mL ampoules

3458B	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
NP	1	16.44	Hospira Pty Limited [HH]

▪ DIPHTHERIA TOXOID + TETANUS TOXOID

diphtheria toxoid 2 Lf/0.5 mL + tetanus toxoid 2 Lf/0.5 mL injection, 10 x 0.5 mL vials

10244E	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
NP	1	129.46	MassBiologics tetanus and diphtheria toxoids adsorbed [CS]

OR

▪ DIPHTHERIA TOXOID + TETANUS TOXOID

diphtheria toxoid 2 international units/0.5 mL + tetanus toxoid 20 international units/0.5 mL injection, 5 x 0.5 mL syringes

3463G	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
NP	2	*129.47	ADT Booster [CS]

▪ FRUSEMIDE

frusemide 20 mg/2 mL injection, 5 x 2 mL ampoules

3466K	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	11.88	[a] Frusemide-Claris [AE] [a] Lasix [SW]	[a] Frusemide Sandoz [SZ]

▪ GLUCAGON HYDROCHLORIDE

glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack

3467L	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
NP	1	47.74	GlucaGen Hypokit [NO]

▪ GLYCERYL TRINITRATE

glyceryl trinitrate 400 microgram/actuation spray, 200 actuations

3475X	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
NP	‡1	22.34	Nitrolingual Pumpspray [SW]

▪ HYOSCINE BUTYLBROMIDE

hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules

3473T	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
NP	1	25.12	Buscopan [BY]

▪ LIGNOCAINE

lignocaine hydrochloride anhydrous 1% (50 mg/5 mL) injection, 5 x 5 mL ampoules

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
10209H	1	35.96	Pfizer Australia Pty Ltd [PF]

NP

▪ METHOXYFLURANE

methoxyflurane 999.9 mg/g inhalation: solution, 3 mL

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
3489P	1	42.59	Penthrox [DV]

▪ METOCLOPRAMIDE

metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
3476Y	1	16.13	Maxolon [IA]

NP

OR

▪ PROCHLORPERAZINE

prochlorperazine mesylate 12.5 mg/mL injection, 10 x 1 mL ampoules

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
3477B	1	20.10	Stemetil [SW]

NP

▪ MIDAZOLAM

midazolam 5 mg/mL injection, 10 x 1 mL ampoules

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
10178Q	1	38.38	Pfizer Australia Pty Ltd [PF]

NP

▪ MORPHINE

morphine sulfate 15 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
3479D	1	22.52	Hospira Pty Limited [HH]

NP

OR

morphine sulfate 30 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
3480E	1	25.02	Hospira Pty Limited [HH]

NP

▪ NALOXONE

naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
10786Q	2	*180.41	Naloxone Hydrochloride (DBL) [HH]

NP

▪ OXYTOCIN

oxytocin 10 units/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
10251M	1	60.42	Oxytocin Sandoz [SZ]

▪ PHYTOMENADIONE

phytomenadione 10 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
10213M	1	23.91	Konakion MM [RO]

▪ PROMETHAZINE

promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules

	Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
3488N	2	*38.01	Hospira Pty Limited [HH]

NP

▪ SALBUTAMOL

salbutamol 100 microgram/actuation inhalation: pressurised, 200 actuations

3495Y NP

Max.Qty Packs	DPMQ $	Brand Name and Manufacturer
‡1	13.63	[a] Asmol CFC-free [AL]
	14.65	[a] Ventolin CFC-free [GK]

OR

salbutamol 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules

3496B NP

Max.Qty Packs	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	14.42	[a] APO-Salbutamol [TX]	[a] Butamol 2.5 [QA]
		[a] GenRx Salbutamol [GX]	[a] Pharmacor Salbutamol 2.5 [CR]
		[a] Salbutamol Actavis [EA]	[a] Salbutamol Sandoz [SZ]
	14.67	[a] Asmol 2.5 uni-dose [AF]	
	14.94	[a] Ventolin Nebules [GK]	

▪ SALBUTAMOL

salbutamol 5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules

3497C NP

Max.Qty Packs	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	14.63	[a] APO-Salbutamol [TX]	[a] Butamol 5 [QA]
		[a] GenRx Salbutamol [GX]	[a] Pharmacor Salbutamol 5 [CR]
		[a] Salbutamol Actavis [EA]	[a] Salbutamol Sandoz [SZ]
	14.88	[a] Asmol 5 uni-dose [AF]	
	15.13	[a] Ventolin Nebules [GK]	

▪ TRAMADOL

tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules

3484J NP

Max.Qty Packs	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	13.98	[a] Tramadol ACT [EA]	[a] Tramadol Sandoz [SZ]
		[a] Tramal 100 [CS]	

General Pharmaceutical Benefits

ALIMENTARY TRACT AND METABOLISM

STOMATOLOGICAL PREPARATIONS

STOMATOLOGICAL PREPARATIONS

Antiinfectives and antiseptics for local oral treatment

AMPHOTERICIN B

amphotericin B 10 mg lozenge, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2931G NP	1	1	..	15.05	16.22	Fungilin [QA]

amphotericin B 10 mg lozenge, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3306B DP	1	..	..	15.05	16.22	Fungilin [QA]

Other agents for local oral treatment

BENZYDAMINE

Restricted benefit

Mucositis

Clinical criteria:

The condition must be radiation induced.

benzydamine hydrochloride 0.15% mouthwash, 500 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1121B NP	‡1	1	..	23.51	24.68	Difflam [IA]

BENZYDAMINE

Restricted benefit

Mucositis

Clinical criteria:

The condition must be radiation induced.

benzydamine hydrochloride 0.15% mouthwash, 500 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5032W DP	‡1	..	..	23.51	24.68	Difflam [IA]

DRUGS FOR ACID RELATED DISORDERS

DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)

H2-receptor antagonists

CIMETIDINE

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

cimetidine 400 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1158Y NP	1	5	..	19.42	20.59	Magicul 400 [AF]

FAMOTIDINE

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

famotidine 20 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2487X NP	1	5	..	14.27	15.44	[a] Ausfam 20 [RW] [a] Famotidine AN [EA] [a] GenRx Famotidine [GX] [a] Pepzan [ED]	[a] Chem mart Famotidine [CH] [a] Famotidine Sandoz [SZ] [a] Pamacid 20 [AF] [a] Terry White Chemists Famotidine [TW]

famotidine 40 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2488Y NP	1	5	..	14.27	15.44	[a] Ausfam 40 [RW] [a] Famotidine AN [EA]	[a] Chem mart Famotidine [CH] [a] Famotidine Sandoz [SZ]

						[a] GenRx Famotidine [GX] [a] Pepzan [ED]	[a] Pamacid 40 [AF] [a] Terry White Chemists Famotidine [TW]

▪ NIZATIDINE

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

nizatidine 150 mg capsule, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1505F NP	1	5	..	20.86	22.03	[a] Nizac [RF]	[a] Tacidine [AF]
			[B]4.63	25.49	22.03	[a] Tazac [RW]	

nizatidine 300 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1504E NP	1	5	..	20.86	22.03	[a] Nizac [RF]	[a] Tacidine [AF]
			[B]4.63	25.49	22.03	[a] Tazac [RW]	

▪ RANITIDINE

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

ranitidine 150 mg/10 mL oral liquid, 300 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8162N NP	2	5	..	*26.17	27.34	Zantac Syrup [AS]

ranitidine 300 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1977C NP	1	5	..	14.56	15.73	[a] APO-Ranitidine [TX] [a] Chem mart Ranitidine [CH] [a] Rani 2 [AF] [a] Ranitidine Sandoz [SZ] [a] Terry White Chemists Ranitidine [TW]	[a] Ausran [RW] [a] GenRx Ranitidine [GX] [a] Ranitidine GH [GQ] [a] Ranoxyl [FM]
			[B]2.00	16.56	15.73	[a] Zantac [AS]	

▪ RANITIDINE

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

Note Pharmaceutical benefits that have the form ranitidine tablet 150 mg (as hydrochloride) and pharmaceutical benefits that have the form ranitidine tablet, effervescent, 150 mg (as hydrochloride) are equivalent for the purposes of substitution.

ranitidine 150 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1978D NP MW	1	5	..	14.56	15.73	[a] APO-Ranitidine [TX] [a] Chem mart Ranitidine [CH] [a] Rani 2 [AF] [a] Ranitidine GH [GQ] [a] Ranoxyl [FM] [a] Ulcaid [RA]	[a] Ausran [RW] [a] GenRx Ranitidine [GX] [a] Ranitidine AN [EA] [a] Ranitidine Sandoz [SZ] [a] Terry White Chemists Ranitidine [TW]
			[B]2.00	16.56	15.73	[a] Zantac [AS]	

ranitidine 150 mg tablet: effervescent, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1937Y NP	2	5	[B]1.40	*16.49	16.26	[a] Zantac [AS]

Proton pump inhibitors

▪ ESOMEPRAZOLE

Note Pharmaceutical benefits that have the form esomeprazole tablet 40 mg and pharmaceutical benefits that have the form esomeprazole capsule 40 mg are equivalent for the purposes of substitution.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Gastro-oesophageal reflux disease

Clinical criteria:

The treatment must be for the healing of gastro-oesophageal reflux disease.

esomeprazole 40 mg capsule, 30

10330Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	33.35	34.52	[a] Esomeprazole ACTAVIS [EA]	[a] Noxicid Caps [AL]

esomeprazole 40 mg tablet: enteric, 30

8601Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	33.35	34.52	[a] Esomeprazole AN [EA] [a] Esomeprazole GH [GQ] [a] Esomeprazole RBX [RA] [a] Nexazole [RW] [a] Nexole [RF]	[a] Esomeprazole Apotex [TX] [a] Esomeprazole GxP [AF] [a] Esomeprazole Sandoz [SZ] [a] Nexium [AP]

▪ ESOMEPRAZOLE

Note Pharmaceutical benefits that have the form esomeprazole tablet 40 mg and pharmaceutical benefits that have the form esomeprazole capsule 40 mg are equivalent for the purposes of substitution.

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

Authority required

Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

Authority required

Scleroderma oesophagus

esomeprazole 40 mg capsule, 30

10331R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	33.35	34.52	[a] Esomeprazole ACTAVIS [EA]	[a] Noxicid Caps [AL]

esomeprazole 40 mg tablet: enteric, 30

3401B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	33.35	34.52	[a] Esomeprazole AN [EA] [a] Esomeprazole GH [GQ] [a] Esomeprazole RBX [RA] [a] Nexazole [RW] [a] Nexole [RF]	[a] Esomeprazole Apotex [TX] [a] Esomeprazole GxP [AF] [a] Esomeprazole Sandoz [SZ] [a] Nexium [AP]

▪ ESOMEPRAZOLE

Note Helicobacter pylori eradication therapy should be considered.

Note Pharmaceutical benefits that have the form esomeprazole tablet 20 mg and pharmaceutical benefits that have the form esomeprazole capsule 20 mg are equivalent for the purposes of substitution.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Gastric ulcer

Treatment Phase: Initial treatment

esomeprazole 20 mg capsule, 30

10295W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	23.95	25.12	[a] Esomeprazole ACTAVIS [EA]	[a] Noxicid Caps [AL]

esomeprazole 20 mg tablet: enteric, 30

8886Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	23.95	25.12	[a] Esomeprazole AN [EA] [a] Esomeprazole GH [GQ] [a] Esomeprazole RBX [RA] [a] Nexazole [RW] [a] Nexole [RF]	[a] Esomeprazole Apotex [TX] [a] Esomeprazole GxP [AF] [a] Esomeprazole Sandoz [SZ] [a] Nexium [AP]

▪ ESOMEPRAZOLE

Note Pharmaceutical benefits that have the form esomeprazole tablet 20 mg and pharmaceutical benefits that have the form esomeprazole capsule 20 mg are equivalent for the purposes of substitution.

Note No increase in the maximum quantity or number of units may be authorised.

Restricted benefit

Gastro-oesophageal reflux disease

Clinical criteria:

The treatment must be maintenance therapy, AND

The condition must be healed.

Restricted benefit
Scleroderma oesophagus
Restricted benefit
Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

esomeprazole 20 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10343J NP	1	5	..	23.95	25.12	[a] Esomeprazole ACTAVIS [EA]	[a] Noxicid Caps [AL]

esomeprazole 20 mg tablet: enteric, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8600P NP	1	5	..	23.95	25.12	[a] Esomeprazole AN [EA] [a] Esomeprazole GH [GQ] [a] Esomeprazole RBX [RA] [a] Nexazole [RW] [a] Nexole [RF]	[a] Esomeprazole Apotex [TX] [a] Esomeprazole GxP [AF] [a] Esomeprazole Sandoz [SZ] [a] Nexium [AP]

▪ LANSOPRAZOLE

Restricted benefit
Gastro-oesophageal reflux disease
Restricted benefit
Scleroderma oesophagus

lansoprazole 15 mg capsule: enteric, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8198L NP	1	5	..	15.71	16.88	Zopral [AF]

lansoprazole 15 mg tablet: orally disintegrating, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9331D NP	1	5	..	15.33	16.50	[a] APO-Lansoprazole ODT [TX] [a] Zopral ODT [AF]	[a] Lansoprazole ODT GH [GQ]
			[B]5.90	21.23	16.50	[a] Zoton FasTabs [PF]	

▪ LANSOPRAZOLE

Note Pharmaceutical benefits that have the form lansoprazole capsule 30 mg and pharmaceutical benefits that have the form lansoprazole tablet 30 mg (orally disintegrating) are equivalent for the purposes of substitution.

Restricted benefit
Gastro-oesophageal reflux disease
Restricted benefit
Scleroderma oesophagus

lansoprazole 30 mg capsule: enteric, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2241Y NP	1	5	..	19.26	20.43	[a] APO-Lansoprazole [TX] [a] Zopral [AF]	[a] Lanzopran [RA]

lansoprazole 30 mg tablet: orally disintegrating, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9478W NP	1	5	..	19.26	20.43	[a] APO-Lansoprazole ODT [TX] [a] Zopral ODT [AF]	[a] Lansoprazole ODT GH [GQ]
			[B]5.89	25.15	20.43	[a] Zoton FasTabs [PF]	

▪ LANSOPRAZOLE

Note Helicobacter pylori eradication therapy should be considered.
Note Pharmaceutical benefits that have the form lansoprazole capsule 30 mg and pharmaceutical benefits that have the form lansoprazole tablet 30 mg (orally disintegrating) are equivalent for the purposes of substitution.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit
Peptic ulcer
Treatment Phase: Initial treatment

lansoprazole 30 mg capsule: enteric, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2240X NP	1	1	..	19.26	20.43	[a] APO-Lansoprazole [TX] [a] Zopral [AF]	[a] Lanzopran [RA]

lansoprazole 30 mg tablet: orally disintegrating, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9477T NP	1	1	..	19.26	20.43	[a] APO-Lansoprazole ODT [TX] [a] Zopral ODT [AF]	[a] Lansoprazole ODT GH [GQ]
			[B]5.89	25.15	20.43	[a] Zoton FasTabs [PF]	

▪ OMEPRAZOLE

Restricted benefit

Gastro-oesophageal reflux disease

Restricted benefit

Scleroderma oesophagus

Restricted benefit

Zollinger-Ellison syndrome

omeprazole 10 mg tablet: enteric, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8332M NP	1	5	..	14.58	15.75	Losec Tablets [AP]

▪ OMEPRAZOLE

Note Helicobacter pylori eradication therapy should be considered.

Note Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Peptic ulcer

Treatment Phase: Initial treatment

omeprazole 20 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1326T NP	1	1	..	15.52	16.69	[a] APO-Omeprazole [TX] [a] Omeprazole Sandoz [HX] [a] Pemzo [RW] [a] Probitor [SZ]	[a] Maxor [AF] [a] Omepro-GA [EA] [a] Pharmacor Omeprazole 20 [CR]

omeprazole 20 mg tablet: enteric, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8331L NP	1	1	..	15.52	16.69	[a] APO-Omeprazole [TX] [a] Meprazol [SZ] [a] Omeprazole-GA [ED] [a] Omeprazole RBX [RA] [a] Terry White Chemists Omeprazole [TW]	[a] Chem mart Omeprazole [CH] [a] Omeprazole AN [EA] [a] Omeprazole generichealth [GQ] [a] Ozmep [ZP]

omeprazole 20 mg tablet: enteric, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9109K NP	1	1	..	15.52	16.69	[a] Acimax Tablets [AL] [a] Omeprazole Sandoz [SZ]	[a] Omepral [TX]
			[B]3.06	18.58	16.69	[a] Losec Tablets [AP]	

▪ OMEPRAZOLE

Note Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.

Restricted benefit

Gastro-oesophageal reflux disease

Restricted benefit

Scleroderma oesophagus

Restricted benefit

Zollinger-Ellison syndrome

omeprazole 20 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1327W NP	1	5	..	15.52	16.69	[a] APO-Omeprazole [TX] [a] Omeprazole Sandoz [HX] [a] Pemzo [RW] [a] Probitor [SZ]	[a] Maxor [AF] [a] Omepro-GA [EA] [a] Pharmacor Omeprazole 20 [CR]

omeprazole 20 mg tablet: enteric, 30

8333N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.52	16.69	[a] APO-Omeprazole [TX] [a] Meprazol [SZ] [a] Omeprazole-GA [ED] [a] Omeprazole RBX [RA] [a] Terry White Chemists Omeprazole [TW]	[a] Chem mart Omeprazole [CH] [a] Omeprazole AN [EA] [a] Omeprazole generichealth [GQ] [a] Ozmep [ZP]

omeprazole 20 mg tablet: enteric, 30

9110L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.52	16.69	[a] Acimax Tablets [AL] [a] Omeprazole Sandoz [SZ]	[a] Omepral [TX]
			[B]3.06	18.58	16.69	[a] Losec Tablets [AP]	

▪ PANTOPRAZOLE

Note Helicobacter pylori eradication therapy should be considered.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit
Peptic ulcer
Treatment Phase: Initial treatment

pantoprazole 40 mg granules: enteric-coated, 30 sachets

9423Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	31.54	32.71	Somac [NQ]

pantoprazole 40 mg tablet: enteric, 30

8007K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	13.91	15.08	[a] APO-Pantoprazole [TX] [a] Chem mart Pantoprazole [CH] [a] Ozpan [RA] [a] Panto [TK] [a] Pantoprazole Actavis [ED] [a] Pantoprazole-GA [EF] [a] Pantoprazole Sandoz [SZ] [a] Somac [NQ] [a] Terry White Chemists Pantoprazole [TW]	[a] APOTEX-Pantoprazole [GX] [a] I-Pantoprazole [CR] [a] Panthron [ER] [a] Pantofast 40 [RZ] [a] Pantoprazole AN [EA] [a] Pantoprazole GH [GQ] [a] Salpraz [AF] [a] Sozol [RW] [a] Topra 40 [DO]

▪ PANTOPRAZOLE

Restricted benefit
Gastro-oesophageal reflux disease
Restricted benefit
Scleroderma oesophagus
Restricted benefit
Zollinger-Ellison syndrome

pantoprazole 20 mg tablet: enteric, 30

8399C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.12	13.29	[a] APO-Pantoprazole [TX] [a] Chem mart Pantoprazole [CH] [a] Ozpan [RA] [a] Panto [TK] [a] Pantoprazole AN [EA] [a] Pantoprazole GH [GQ] [a] Salpraz [AF] [a] Sozol [RW]	[a] APOTEX-Pantoprazole [GX] [a] I-Pantoprazole [CR] [a] Panthron [ER] [a] Pantofast 20 [RZ] [a] Pantoprazole-GA [EF] [a] Pantoprazole Sandoz [SZ] [a] Somac [NQ] [a] Terry White Chemists Pantoprazole [TW]

pantoprazole 40 mg granules: enteric-coated, 30 sachets

9424B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	31.54	32.71	Somac [NQ]

pantoprazole 40 mg tablet: enteric, 30

8008L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.91	15.08	[a] APO-Pantoprazole [TX] [a] Chem mart Pantoprazole [CH]	[a] APOTEX-Pantoprazole [GX] [a] I-Pantoprazole [CR]

					[a] Ozpan [RA]	[a] Panthron [ER]
					[a] Panto [TK]	[a] Pantofast 40 [RZ]
					[a] Pantoprazole Actavis [ED]	[a] Pantoprazole AN [EA]
					[a] Pantoprazole-GA [EF]	[a] Pantoprazole GH [GQ]
					[a] Pantoprazole Sandoz [SZ]	[a] Salpraz [AF]
					[a] Somac [NQ]	[a] Sozol [RW]
					[a] Terry White Chemists Pantoprazole [TW]	[a] Topra 40 [DO]

▪ RABEPRAZOLE

Restricted benefit

Gastro-oesophageal reflux disease

Restricted benefit

Scleroderma oesophagus

rabeprazole sodium 10 mg tablet: enteric, 28

8507R (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	15.73	16.90	[a] APO-Rabeprazole [TX]	[a] Chem mart Rabeprazole [CH]
					[a] Parbezol [RW]	[a] Pariet [JC]
					[a] Parzol 10 [ZP]	[a] Prabez [AF]
					[a] Rabeprazole AN [EA]	[a] Rabeprazole-DRLA [RZ]
					[a] Rabeprazole generichealth [GQ]	[a] Rabeprazole Sandoz [SZ]
					[a] Razit 10 [DO]	[a] Terry White Chemists Rabeprazole [TW]

rabeprazole sodium 20 mg tablet: enteric, 30

8508T (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	15.73	16.90	[a] APO-Rabeprazole [TX]	[a] Chem mart Rabeprazole [CH]
					[a] Parbezol [RW]	[a] Pariet [JC]
					[a] Parzol 20 [ZP]	[a] Prabez [AF]
					[a] Rabeprazole Actavis 20 [ED]	[a] Rabeprazole AN [EA]
					[a] Rabeprazole-DRLA [RZ]	[a] Rabeprazole generichealth [GQ]
					[a] Rabeprazole Sandoz [SZ]	[a] Rabeprazole SUN [RN]
					[a] Razit 20 [DO]	[a] Terry White Chemists Rabeprazole [TW]
					[a] Zabep [AL]	

▪ RABEPRAZOLE

Note Helicobacter pylori eradication therapy should be considered.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Peptic ulcer

Treatment Phase: Initial treatment

rabeprazole sodium 20 mg tablet: enteric, 30

8509W (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	15.73	16.90	[a] APO-Rabeprazole [TX]	[a] Chem mart Rabeprazole [CH]
					[a] Parbezol [RW]	[a] Pariet [JC]
					[a] Parzol 20 [ZP]	[a] Prabez [AF]
					[a] Rabeprazole Actavis 20 [ED]	[a] Rabeprazole AN [EA]
					[a] Rabeprazole-DRLA [RZ]	[a] Rabeprazole generichealth [GQ]
					[a] Rabeprazole Sandoz [SZ]	[a] Rabeprazole SUN [RN]
					[a] Razit 20 [DO]	[a] Terry White Chemists Rabeprazole [TW]
					[a] Zabep [AL]	

Combinations for eradication of Helicobacter pylori

▪ ESOMEPRAZOLE (&) CLARITHROMYCIN (&) AMOXYCILLIN

Note Pharmaceutical benefits that have the form pack containing 14 tablets (enteric coated) containing esomeprazole 20 mg (as magnesium trihydrate), 14 tablets clarithromycin 500 mg and 28 capsules amoxycillin 500 mg (as trihydrate) and pack containing 14 tablets (enteric coated) containing esomeprazole 20 mg (as magnesium), 14 tablets clarithromycin 500 mg and 28 capsules amoxycillin 500 mg (as trihydrate) are equivalent for the purposes of substitution.

Restricted benefit

Eradication of Helicobacter pylori

Clinical criteria:

The condition must be associated with peptic ulcer disease.

esomeprazole 20 mg tablet: enteric [14 tablets] (&) clarithromycin 500 mg tablet [14 tablets] (&) amoxycillin 500 mg capsule [28 capsules], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10759G NP	‡1	..	..	44.47	38.30	[a] ESOMEPRAZOLE SANDOZ Hp7 [SZ]

esomeprazole 20 mg tablet: enteric [14 tablets] (&) clarithromycin 500 mg tablet [14 tablets] (&) amoxycillin 500 mg capsule [28 capsules], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8738X NP	‡1	..	..	44.47	38.30	[a] Nexium Hp7 [AP]

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

▪ ALGINATE SODIUM + CALCIUM CARBONATE + BICARBONATE

Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

alginate sodium 500 mg/10 mL + calcium carbonate 160 mg/10 mL + sodium bicarbonate 267 mg/10 mL oral liquid, 500 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2014B NP	2	5	..	*17.45	18.62	Gaviscon P [RC]

▪ SUCRALFATE

sucralfate 1 g tablet, 120

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2055E NP	1	2	..	25.27	26.44	[a] Ulcyte [AF]
			[B]2.00	27.27	26.44	[a] Carafate [AS]

▪ DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

BELLADONNA AND DERIVATIVES, PLAIN

Belladonna alkaloids, tertiary amines

▪ ATROPINE SULFATE

ATROPINE Injection 600 micrograms in 1 mL, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5022H DP	1	..	..	22.09	23.26	Pfizer Australia Pty Ltd [PF]

▪ ATROPINE SULFATE

Note Shared Care Model:

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

ATROPINE Injection 600 micrograms in 1 mL, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1089H NP	1	1	..	22.09	23.26	Pfizer Australia Pty Ltd [PF]

PROPULSIVES

Propulsives

▪ DOMPERIDONE

domperidone 10 mg tablet, 25

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1347X NP	1	..	..	12.46	13.63	Motilium [JC]

▪ METOCLOPRAMIDE

metoclopramide hydrochloride 10 mg tablet, 25

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1207M NP MW	1	..	..	11.55	12.72	[a] APO-Metoclopramide [TX] [a] Metoclopramide AN [EA] [a] Pramin [AF]	[a] Metoclopramide Actavis [ED] [a] Metoclopramide RBX [RA]
			[B]1.91	13.46	12.72	[a] Maxolon [IA]	

metoclopramide hydrochloride 10 mg tablet, 25

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5151D DP	1	..	..	11.55	12.72	[a] APO-Metoclopramide [TX] [a] Metoclopramide AN [EA] [a] Pramin [AF]	[a] Metoclopramide Actavis [ED] [a] Metoclopramide RBX [RA]
			[B]1.91	13.46	12.72	[a] Maxolon [IA]	

metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1206L NP MW	1	..	..	16.13	17.30	Maxolon [IA]

metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5153F DP	1	..	..	16.13	17.30	Maxolon [IA]

ANTIEMETICS AND ANTINAUSEANTS

ANTIEMETICS AND ANTINAUSEANTS

Serotonin (5HT3) antagonists

GRANISETRON

Restricted benefit

Nausea and vomiting

Clinical criteria:

The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

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

granisetron 3 mg/3 mL injection, 3 mL ampoule

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8729K NP	1	..	..	13.57	14.74	[a] Granisetron-AFT [AE] [a] Granisetron Kabi [PK]	[a] GRANISETRON APOTEX [TX] [a] Kytril [RO]

GRANISETRON

Authority required (STREAMLINED)

4092

Nausea and vomiting

Clinical criteria:

The condition must be associated with radiotherapy being used to treat malignancy.

granisetron 3 mg/3 mL injection, 3 mL ampoule

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8730L NP	1	..	..	13.57	14.74	[a] Granisetron-AFT [AE] [a] Granisetron Kabi [PK]	[a] GRANISETRON APOTEX [TX] [a] Kytril [RO]

GRANISETRON

Authority required (STREAMLINED)

4102

Nausea and vomiting

Clinical criteria:

The condition must be associated with radiotherapy being used to treat malignancy.

granisetron 2 mg tablet, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8873B NP	1	1	..	60.36	38.30	Kytril [RO]

GRANISETRON

Restricted benefit

Nausea and vomiting

Clinical criteria:

The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

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

granisetron 2 mg tablet, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8728J NP	2	..	..	*30.41	31.58	Kytril [RO]

▪ NETUPITANT + PALONOSETRON

Note No increase in the maximum number of repeats may be authorised.
Note No increase in the maximum quantity or number of units may be authorised.
Note This medicine is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.

Authority required (STREAMLINED)
5991
Nausea and vomiting
Clinical criteria:
The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, AND
The treatment must be in combination with dexamethasone, AND
Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.
No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

Authority required (STREAMLINED)
5994
Nausea and vomiting
Clinical criteria:
The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer, AND
The treatment must be in combination with dexamethasone, AND
Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.
No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

netupitant 300 mg + palonosetron 500 microgram capsule, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10731T NP	‡1	5	..	121.18	38.30	Akynzeo [ZD]

▪ ONDANSETRON

Authority required (STREAMLINED)
4102
Nausea and vomiting
Clinical criteria:
The condition must be associated with radiotherapy being used to treat malignancy.

ondansetron 4 mg tablet, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1594X NP	1	1	..	25.31	26.48	[a] APO-Ondansetron [TX] [a] Ondansetron-DRLA [RZ] [a] Onsetron 4 [ZP] [a] Zofran [AS]	[a] Ondansetron AN [EA] [a] Ondansetron SZ [HX] [a] Zilfojim 4 [DO]

ondansetron 4 mg/5 mL oral liquid, 50 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8233H NP	‡1	1	..	97.27	38.30	Zofran syrup 50 mL [AS]

ondansetron 8 mg tablet, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1595Y NP	1	1	..	33.75	34.92	[a] APO-Ondansetron [TX] [a] Ondansetron-DRLA [RZ] [a] Onsetron 8 [ZP] [a] Zofran [AS]	[a] Ondansetron AN [EA] [a] Ondansetron SZ [HX] [a] Zilfojim 8 [DO]

▪ ONDANSETRON

Authority required (STREAMLINED)
4092
Nausea and vomiting
Clinical criteria:
The condition must be associated with radiotherapy being used to treat malignancy.

ondansetron 4 mg/2 mL injection, 2 mL ampoule

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1596B NP	1	..	..	10.81	11.98	[a] Ondansetron Alphapharm [AF] [a] Ondansetron Kabi [PK]	[a] Ondansetron-Claris [AE] [a] Onsetron [ZP]

ondansetron 8 mg/4 mL injection, 4 mL ampoule

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1597C NP	1	..	..	11.03	12.20	[a] Ondansetron Alphapharm [AF] [a] Ondansetron Kabi [PK]	[a] Ondansetron-Claris [AE] [a] Onsetron [ZP]

▪ ONDANSETRON

Restricted benefit

Nausea and vomiting

Clinical criteria:

The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

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

ondansetron 4 mg tablet, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8224W NP	1	..	..	16.38	17.55	[a] APO-Ondansetron [TX] [a] Ondansetron-DRLA [RZ] [a] Onsetron 4 [ZP]	[a] Ondansetron AN [EA] [a] Ondansetron SZ [HX] [a] Zofran [AS]

ondansetron 8 mg tablet, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8225X NP	1	..	..	19.75	20.92	[a] APO-Ondansetron [TX] [a] Ondansetron-DRLA [RZ] [a] Onsetron 8 [ZP]	[a] Ondansetron AN [EA] [a] Ondansetron SZ [HX] [a] Zofran [AS]

▪ ONDANSETRON

Restricted benefit

Nausea and vomiting

Clinical criteria:

The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

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

ondansetron 4 mg/2 mL injection, 2 mL ampoule

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8226Y NP	1	..	..	10.81	11.98	[a] Ondansetron Alphapharm [AF] [a] Ondansetron Kabi [PK]	[a] Ondansetron-Claris [AE] [a] Onsetron [ZP]

ondansetron 8 mg/4 mL injection, 4 mL ampoule

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8227B NP	1	..	..	11.03	12.20	[a] Ondansetron Alphapharm [AF] [a] Ondansetron Kabi [PK]	[a] Ondansetron-Claris [AE] [a] Onsetron [ZP]

▪ ONDANSETRON

Restricted benefit

Nausea and vomiting

Clinical criteria:

The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

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

ondansetron 4 mg/5 mL oral liquid, 50 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9441X NP	‡1	..	..	97.27	38.30	Zofran syrup 50 mL [AS]

▪ ONDANSETRON

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

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

Restricted benefit

Nausea and vomiting

Clinical criteria:

The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

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

ONDANSETRON Tablet (orally disintegrating) 4 mg, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5470X NP	1	..	..	16.38	17.55	[a] Ondansetron AN ODT [EA] [a] Ondansetron ODT GH [GQ] [a] Onsetron ODT 4 [ED]	[a] Ondansetron ODT-DRLA [RZ] [a] Ondansetron SZ ODT [HX]

ONDANSETRON Tablet (orally disintegrating) 8 mg, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5471Y NP	1	..	..	19.75	20.92	[a] Ondansetron AN ODT [EA] [a] Ondansetron ODT GH [GQ] [a] Onsetron ODT 8 [ED]	[a] Ondansetron ODT-DRLA [RZ] [a] Ondansetron SZ ODT [HX]

ondansetron 4 mg wafer, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8410P NP	1	..	..	16.38	17.55	[a] Zofran Zydis [AS]

ondansetron 8 mg wafer, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8411Q NP	1	..	..	19.75	20.92	[a] Zofran Zydis [AS]

▪ ONDANSETRON

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

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

Authority required (STREAMLINED)

5777

Nausea and vomiting

Clinical criteria:

The condition must be associated with radiotherapy being used to treat malignancy.

ONDANSETRON Tablet (orally disintegrating) 4 mg, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5472B NP	1	1	..	25.31	26.48	[a] Ondansetron AN ODT [EA] [a] Ondansetron ODT GH [GQ] [a] Onsetron ODT 4 [ED]	[a] Ondansetron ODT-DRLA [RZ] [a] Ondansetron SZ ODT [HX] [a] Zilfojim ODT 4 [DO]

ONDANSETRON Tablet (orally disintegrating) 8 mg, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5473C NP	1	1	..	33.75	34.92	[a] Ondansetron AN ODT [EA] [a] Ondansetron ODT GH [GQ] [a] Onsetron ODT 8 [ED]	[a] Ondansetron ODT-DRLA [RZ] [a] Ondansetron SZ ODT [HX] [a] Zilfojim ODT 8 [DO]

ondansetron 4 mg wafer, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8412R NP	1	1	..	25.31	26.48	[a] Zofran Zydis [AS]

ondansetron 8 mg wafer, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8413T NP	1	1	..	33.75	34.92	[a] Zofran Zydis [AS]

▪ PALONOSETRON

Note No increase in the maximum quantity or number of units may be authorised.

Note This drug is not PBS-subsidised for administration with oral 5-HT3 antagonists.

Restricted benefit

Nausea and vomiting

Clinical criteria:

The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

palonosetron 250 microgram/5 mL injection, 5 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5295Q NP	1	..	..	45.51	38.30	Aloxi [ZD]

▪ TROPISETRON

Restricted benefit

Nausea and vomiting

Clinical criteria:

The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

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

tropisetron 5 mg/5 mL injection, 5 mL ampoule

2746M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	16.74	17.91	Tropisetron-AFT [AE]

Other antiemetics

▪ APREPITANT

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

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4211

Nausea and vomiting

Clinical criteria:

The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, AND

The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone, AND

Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.

No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.

Authority required (STREAMLINED)

4215

Nausea and vomiting

Clinical criteria:

The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer, AND

The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone, AND

Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.

No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.

Authority required (STREAMLINED)

4213

Nausea and vomiting

Clinical criteria:

The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy, AND

The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle, AND

Patient must have had a prior episode of chemotherapy induced nausea or vomiting, AND

Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following intravenous chemotherapy agents: arsenic trioxide; azacitidine; carboplatin; cyclophosphamide at a dose of less than 1500 mg per square metre per day; cytarabine at a dose of greater than 1 g per square metre per day; dactinomycin; daunorubicin; doxorubicin; epirubicin; fotemustine; idarubicin; ifosfamide; irinotecan; melphalan; methotrexate at a dose of 250 mg to 1 g per square metre; oxaliplatin; raltitrexed.

No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.

Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle.

aprepitant 165 mg capsule, 1

2518M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	123.89	38.30	Emend [MK]

▪ PROCHLORPERAZINE

Caution Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only.

prochlorperazine maleate 5 mg tablet, 25

5205Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	11.66	12.83	[a] APO-Prochlorperazine [TX] [a] ProCalm [RW] [a] Prochlorperazine-GA [ED] [a] Stemzine [AV]	[a] Pharmacor Prozine 5 [CR] [a] Prochlorperazine AN [EA] [a] Prochlorperazine GH [GQ]
			[B]3.00	14.66	12.83	[a] Stemetil [SW]	

prochlorperazine mesylate 12.5 mg/mL injection, 10 x 1 mL ampoules

5206B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	20.10	21.27	Stemetil [SW]

▪ PROCHLORPERAZINE

Caution Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only.

Note As prochlorperazine may be associated with parkinsonism and tardive dyskinesia it should be used for short-term treatment only. However, authorities for increased maximum quantities and/or repeats of prochlorperazine tablets will be granted for the treatment of emesis associated with malignant disease.

prochlorperazine maleate 5 mg tablet, 25

2893G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	11.66	12.83	[a] APO-Prochlorperazine [TX] [a] ProCalm [RW] [a] Prochlorperazine-GA [ED] [a] Stemzine [AV]	[a] Pharmacor Prozine 5 [CR] [a] Prochlorperazine AN [EA] [a] Prochlorperazine GH [GQ]
			[B]3.00	14.66	12.83	[a] Stemetil [SW]	

prochlorperazine mesylate 12.5 mg/mL injection, 10 x 1 mL ampoules

2369Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	20.10	21.27	Stemetil [SW]

▪ PROMETHAZINE

promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules

3374N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	2	..	..	*38.01	38.30	Hospira Pty Limited [HH]

▪ BILE AND LIVER THERAPY

BILE THERAPY

Bile acid preparations

▪ URSODEOXYCHOLIC ACID

Note Not for use in the treatment of sclerosing cholangitis or cholelithiasis.

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

Authority required (STREAMLINED)
5757
Primary biliary cirrhosis

ursodeoxycholic acid 250 mg capsule, 100

8448P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*306.81	38.30	[a] Ursodox GH [GQ] [a] Ursosan [BZ]	[a] Ursofalk [OA]

▪ DRUGS FOR CONSTIPATION

DRUGS FOR CONSTIPATION

Contact laxatives

▪ BISACODYL

Restricted benefit
Constipation
Clinical criteria:
Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

Restricted benefit
Constipation
Clinical criteria:
Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

Restricted benefit
Constipation
Clinical criteria:
Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

Restricted benefit
Constipation
Clinical criteria:
Patient must be receiving palliative care.
Restricted benefit
Terminal malignant neoplasia
Restricted benefit
Anorectal congenital abnormalities
Restricted benefit
Megacolon

bisacodyl 5 mg tablet: enteric, 200

1259G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	17.11	18.28	Lax-Tab [AE]

▪ BISACODYL

Restricted benefit
Constipation
Clinical criteria:
Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.
Restricted benefit
Constipation
Clinical criteria:
Patient must be receiving palliative care.
Restricted benefit
Constipation
Clinical criteria:
Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.
Population criteria:
Patient must identify as Aboriginal or Torres Strait Islander.
Restricted benefit
Constipation
Clinical criteria:
Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.
Population criteria:
Patient must identify as Aboriginal or Torres Strait Islander.
Restricted benefit
Terminal malignant neoplasia
Population criteria:
Patient must identify as Aboriginal or Torres Strait Islander.
Restricted benefit
Anorectal congenital abnormalities
Population criteria:
Patient must identify as Aboriginal or Torres Strait Islander.
Restricted benefit
Megacolon
Population criteria:
Patient must identify as Aboriginal or Torres Strait Islander.

bisacodyl 10 mg suppository, 10

1260H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	5	..	*23.04	24.21	[a] Petrus Bisacodyl Suppositories [PP]
		[B]1.29	*24.33	24.21	[a] Dulcolax [BY]

bisacodyl 10 mg suppository, 12

1258F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	4	..	*20.76	21.93	Petrus Bisacodyl Suppositories [PP]

Bulk-forming laxatives

▪ RHAMNUS FRANGULA + STERCULIA

Restricted benefit
Constipation
Clinical criteria:
Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

Restricted benefit
Constipation
Clinical criteria:
Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.
Restricted benefit
Constipation
Clinical criteria:
Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.
Restricted benefit
Constipation
Clinical criteria:
Patient must be receiving palliative care.
Restricted benefit
Terminal malignant neoplasia
Restricted benefit
Anorectal congenital abnormalities
Restricted benefit
Megacolon

rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1104D NP	‡1	1	..	26.90	28.07	Normacol Plus [NE]

Osmotically acting laxatives

▪ MACROGOL-3350

Note Pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 510 g and pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets are equivalent for the purposes of substitution.

Restricted benefit
Constipation
Clinical criteria:
Patient must have malignant neoplasia.
Restricted benefit
Constipation
Clinical criteria:
Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function, AND
The condition must be unresponsive to other oral therapies.
Restricted benefit
Constipation
Clinical criteria:
Patient must be receiving palliative care.
Restricted benefit
Chronic constipation
Clinical criteria:
The condition must be inadequately controlled with first line interventions such as bulk-forming agents.
Restricted benefit
Faecal impaction
Clinical criteria:
The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2373X NP	‡1	5	..	20.69	21.86	[a] Herron ClearLax [ON]

macrogol-3350 1 g/g oral liquid: powder for, 510 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3416T NP	‡1	5	..	20.69	21.86	[a] OsmoLax [KY]

▪ MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE

Restricted benefit
Constipation
Clinical criteria:
Patient must have malignant neoplasia.
Restricted benefit
Constipation

Clinical criteria:
Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function, AND
The condition must be unresponsive to other oral therapies.

Restricted benefit
Constipation
Clinical criteria:
Patient must be receiving palliative care.

Restricted benefit
Chronic constipation
Clinical criteria:
The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

Restricted benefit
Faecal impaction
Clinical criteria:
The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8612G NP	‡1	5	..	20.69	21.86	[a] APO-MACROGOL plus ELECTROLYTES [TX] [a] LaxaCon [EA] [a] Macrovic [RF] [a] Movicol [NE]	[a] Chemists' Own Macrogol with Electrolytes [RW] [a] lax-sachets [AE] [a] Molaxole [HM]

macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10126Y NP	2	5	..	*24.13	25.30	Movicol Liquid [NE]

Enemas

▪ BISACODYL

Restricted benefit
Constipation
Clinical criteria:
Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

Restricted benefit
Constipation
Clinical criteria:
Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

Restricted benefit
Constipation
Clinical criteria:
Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

Restricted benefit
Constipation
Clinical criteria:
Patient must be receiving palliative care.

Restricted benefit
Terminal malignant neoplasia

Restricted benefit
Anorectal congenital abnormalities

Restricted benefit
Megacolon

bisacodyl 10 mg/5 mL enema, 25 x 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1263L NP	‡1	2	..	37.83	38.30	Bisalax [AS]

▪ SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM

Restricted benefit
Constipation
Clinical criteria:
Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

Restricted benefit

Constipation
Clinical criteria:
Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.
Restricted benefit
Constipation
Clinical criteria:
Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.
Restricted benefit
Constipation
Clinical criteria:
Patient must be receiving palliative care.
Restricted benefit
Terminal malignant neoplasia
Restricted benefit
Anorectal congenital abnormalities
Restricted benefit
Megacolon

sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL

2091C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*32.91	34.08	[a] Micolette [AE]	[a] Microlax [JT]

ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS

INTESTINAL ANTIINFECTIVES

Antibiotics

NYSTATIN

nystatin 500 000 units capsule, 50

1699K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	19.97	21.14	Nilstat [QA]

nystatin 500 000 units capsule, 50

3345C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	19.97	21.14	Nilstat [QA]

nystatin 500 000 units tablet, 50

1696G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	19.97	21.14	Nilstat [QA]

nystatin 500 000 units tablet, 50

3342X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	19.97	21.14	Nilstat [QA]

RIFAXIMIN

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required
Prevention of hepatic encephalopathy
Clinical criteria:
The treatment must be in combination with lactulose, if lactulose is tolerated, AND
Patient must have had prior episodes of hepatic encephalopathy.
Treatment criteria:
Must be treated by a gastroenterologist or hepatologist or in consultation with a gastroenterologist or hepatologist.

rifaximin 550 mg tablet, 56

10001J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	490.11	38.30	Xifaxan [NE]

VANCOMYCIN

Note Metronidazole has similar efficacy to vancomycin but may have less selective pressure to vancomycin resistant enterococci and is therefore the preferred treatment.

Authority required

Antibiotic associated pseudomembranous colitis
Clinical criteria:
The condition must be due to Clostridium difficile, AND
The condition must be unresponsive to metronidazole.
Authority required
Antibiotic associated pseudomembranous colitis
Clinical criteria:
The condition must be due to Clostridium difficile, AND
Patient must have an intolerance to metronidazole.

vancomycin 125 mg capsule, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3113W	2	..	..	*219.23	38.30	Vancocin [AS]

vancomycin 250 mg capsule, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3114X	2	..	..	*434.29	38.30	Vancocin [AS]

ELECTROLYTES WITH CARBOHYDRATES

Oral rehydration salt formulations

▪ SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRIC ACID

Note Each sachet contains sodium chloride 470 mg, potassium chloride 300 mg, sodium acid citrate 530 mg and glucose 3.56 g.

Restricted benefit
For treatment of a patient identifying as Aboriginal or Torres Strait Islander

sodium chloride 470 mg + potassium chloride 300 mg + glucose monohydrate 3.56 g + sodium acid citrate 530 mg oral liquid: powder for, 10 x 4.9 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3196F NP	‡1	..	..	16.06	17.23	[a] Repalyte New Formulation [SW]	[a] restore O.R.S. [EA]

ANTIPROPULSIVES

Antipropulsives

▪ DIPHENOXYLATE + ATROPINE SULFATE

diphenoxylate hydrochloride 2.5 mg + atropine sulfate 25 microgram tablet, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2501P NP	1	..	..	12.20	13.37	[a] Lofenoxal [IA]
			[B]1.51	13.71	13.37	[a] Lomotil [IV]

▪ LOPERAMIDE

loperamide hydrochloride 2 mg capsule, 12

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1571Q NP	1	..	..	11.91	13.08	[a] Gastrex [CR]	[a] Gastro-Stop Loperamide [AS]
			[B]0.65	12.56	13.08	[a] Imodium [JT]	

INTESTINAL ANTIINFLAMMATORY AGENTS

Corticosteroids acting locally

▪ BUDESONIDE

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

budesonide 2 mg/application enema, 2 x 14 applications

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10034D NP	1	3	..	187.97	38.30	Budenofalk [OA]

▪ HYDROCORTISONE ACETATE

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

Restricted benefit

Proctitis

Restricted benefit

Ulcerative colitis

hydrocortisone acetate 10% enema, 21.1 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1502C NP	2	3	..	*40.01	38.30	Colifoam [HM]

▪ PREDNISOLONE SODIUM PHOSPHATE

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

prednisolone (as sodium phosphate) 20 mg/100 mL enema, 7 x 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1920C NP	4	3	..	*197.57	38.30	Predsol [QA]

▪ PREDNISOLONE SODIUM PHOSPHATE

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

Restricted benefit

Proctitis

Restricted benefit

Ulcerative colitis

prednisolone (as sodium phosphate) 5 mg suppository, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2554K NP	3	3	..	*41.19	38.30	Predsol [QA]

Aminosalicylic acid and similar agents

▪ BALSALAZIDE

Note Not for the treatment of Crohn disease

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

Authority required (STREAMLINED)

4824

Ulcerative colitis

Clinical criteria:

Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR

Patient must be intolerant to sulfasalazine.

balsalazide sodium 750 mg capsule, 180

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8845M NP	1	5	..	112.69	38.30	Colazide [PK]

▪ MESALAZINE

Note Not for the treatment of Crohn disease

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

Authority required (STREAMLINED)

4824

Ulcerative colitis

Clinical criteria:

Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR

Patient must be intolerant to sulfasalazine.

mesalazine 1 g granules: modified release, 100 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8599N NP	1	5	..	255.06	38.30	Salofalk [OA]

mesalazine 1.2 g tablet: modified release, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9353G NP	2	5	..	*390.67	38.30	Mezavant [ZI]

mesalazine 1.5 g granules, 60 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9206M NP	1	5	..	220.93	38.30	Salofalk [OA]

mesalazine 3 g granules, 30 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10257W NP	1	5	..	220.93	38.30	Salofalk [OA]

mesalazine 4 g granules: modified release, 30 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10254Q NP	1	5	..	287.18	38.30	Pentasa [FP]

mesalazine 500 mg granules, 100 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8598M NP	2	5	..	*272.55	38.30	Salofalk [OA]

▪ MESALAZINE

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

Authority required (STREAMLINED)
4873
Ulcerative colitis
Clinical criteria:
Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR
Patient must be intolerant to sulfasalazine.
Authority required (STREAMLINED)
4896
Crohn disease
Clinical criteria:
Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR
Patient must be intolerant to sulfasalazine.

mesalazine 1 g granules: modified release, 120 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2234N NP	1	5	..	305.24	38.30	Pentasa [FP]

mesalazine 1 g tablet: modified release, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3413P NP	2	5	..	*305.25	38.30	Pentasa [FP]

mesalazine 2 g granules: modified release, 60 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2287J NP	1	5	..	287.18	38.30	Pentasa [FP]

mesalazine 250 mg tablet: enteric, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1611T NP	1	5	..	85.57	38.30	Mesasal [AS]

mesalazine 500 mg tablet: enteric, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8731M NP	2	5	..	*272.55	38.30	Salofalk [OA]

mesalazine 500 mg tablet: modified release, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2214M NP	2	5	..	*272.55	38.30	Pentasa [FP]

▪ MESALAZINE

Note Not for the treatment of Crohn disease
Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

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

Restricted benefit

Acute episode of mild to moderate ulcerative proctitis

mesalazine 1 g suppository, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5461K NP	1	1	..	122.67	38.30	Salofalk [OA]

mesalazine 1 g suppository, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8752P NP	1	1	..	122.67	38.30	Pentasa [FP]

▪ MESALAZINE

Note Not for the treatment of Crohn disease

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

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

Authority required (STREAMLINED)

4888

Acute episode of mild to moderate ulcerative colitis

mesalazine 1 g/100 mL enema, 7 x 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8753Q NP	4	1	..	*310.73	38.30	Pentasa [FP]

mesalazine 1 g/application enema, 14 applications

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8768L NP	4	1	..	*310.73	38.30	Salofalk [OA]

mesalazine 2 g/60 mL enema, 7 x 60 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8616L NP	4	1	..	*310.73	38.30	Salofalk [OA]

mesalazine 4 g/60 mL enema, 7 x 60 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8617M NP	4	1	..	*418.53	38.30	Salofalk [OA]

▪ OLSALAZINE

Note Not for the treatment of Crohn disease

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

Authority required (STREAMLINED)

4824

Ulcerative colitis

Clinical criteria:

Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR

Patient must be intolerant to sulfasalazine.

olsalazine sodium 250 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1728Y NP	1	5	..	57.91	38.30	Dipentum [IX]

olsalazine sodium 500 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8086N NP	1	5	..	94.08	38.30	Dipentum [IX]

▪ SULFASALAZINE

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

SULFASALAZINE Tablet 500 mg (enteric coated), 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2096H NP	2	5	..	*53.77	38.30	[a] Pyralin EN [FZ]
			[B]3.48	*57.25	38.30	[a] Salazopyrin-EN [PF]

sulfasalazine 500 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2093E NP	2	5	..	*49.79	38.30	Salazopyrin [PF]

▪ SULFASALAZINE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

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

SULFASALAZINE Tablet 500 mg (enteric coated), 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9209Q	2	11	..	*53.77	38.30	[a] Pyralin EN [FZ]
			[B]3.48	*57.25	38.30	[a] Salazopyrin-EN [PF]

sulfasalazine 500 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9208P	2	11	..	*49.79	38.30	Salazopyrin [PF]

▪ DIGESTIVES, INCL. ENZYMES

DIGESTIVES, INCL. ENZYMES

Enzyme preparations

▪ PANCREATIC EXTRACT

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

pancreatic extract 10 000 units capsule: modified release, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8020D NP	5	10	..	*163.53	38.30	Creon 10,000 [GO]

pancreatic extract 25 000 units capsule: modified release, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8021E NP	2	10	..	*132.49	38.30	Creon 25,000 [GO]

pancreatic extract 40 000 units capsule: modified release, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9412J NP	2	10	..	*206.21	38.30	Creon 40,000 [GO]

pancreatic extract 5000 units/100 mg granules: enteric-coated, 20 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5453B NP	3	10	..	*127.32	38.30	Creon Micro [GO]

▪ PANCREATIC EXTRACT

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit
Cystic fibrosis
Clinical criteria:
Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

pancreatic extract 10 000 units capsule: modified release, 100

9226N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	5	21	..	*163.53	38.30	Creon 10,000 [GO]

pancreatic extract 25 000 units capsule: modified release, 100

9227P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	21	..	*132.49	38.30	Creon 25,000 [GO]

pancreatic extract 40 000 units capsule: modified release, 100

9413K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	21	..	*206.21	38.30	Creon 40,000 [GO]

pancreatic extract 5000 units/100 mg granules: enteric-coated, 20 g

5454C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	3	21	..	*127.32	38.30	Creon Micro [GO]

▪ PANCRELIPASE

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

pancrelipase 25 000 units capsule, 100

8366H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	10	..	*123.97	38.30	Panzytrat 25000 [TM]

▪ PANCRELIPASE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit
Cystic fibrosis
Clinical criteria:
Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

pancrelipase 25 000 units capsule, 100

9229R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	21	..	*123.97	38.30	Panzytrat 25000 [TM]

▪ DRUGS USED IN DIABETES

INSULINS AND ANALOGUES

Insulins and analogues for injection, fast-acting

▪ INSULIN ASPART

insulin aspart 100 units/mL injection, 1 x 10 mL vial

8571D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	5	2	..	*142.48	38.30	NovoRapid [NO]

insulin aspart 100 units/mL injection, 5 x 3 mL cartridges

8435Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*239.93	38.30	NovoRapid FlexPen [NF]	NovoRapid Penfill 3 mL [NO]

▪ INSULIN GLULISINE

insulin glulisine 100 units/mL injection, 1 x 10 mL vial

9224L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	5	2	..	*142.48	38.30	Apidra [SW]

insulin glulisine 100 units/mL injection, 5 x 3 mL cartridges

1921D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*239.93	38.30	Apidra [AV]	Apidra SoloStar [SW]

▪ INSULIN LISPRO

insulin lispro 100 units/mL injection, 1 x 10 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8084L NP	5	2	..	*142.48	38.30	Humalog [LY]

insulin lispro 100 units/mL injection, 5 x 3 mL cartridges

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8212F NP	5	1	..	*239.93	38.30	Humalog [LY]	Humalog KwikPen [KP]

▪ INSULIN NEUTRAL BOVINE

Authority required

Diabetes mellitus

Clinical criteria:

Patient must be intolerant to human insulin.

insulin neutral bovine 100 units/mL injection, 1 x 10 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1713E NP	5	2	..	*374.13	38.30	Hypurin Neutral [AS]

▪ INSULIN NEUTRAL HUMAN

insulin neutral human 100 units/mL injection, 1 x 10 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1531N NP	5	2	..	*120.43	38.30	Actrapid [NO]	Humulin R [LY]

insulin neutral human 100 units/mL injection, 5 x 3 mL cartridges

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1762R NP	5	1	..	*200.68	38.30	Actrapid Penfill 3 mL [NO]	Humulin R [LY]

Insulins and analogues for injection, intermediate-acting

▪ INSULIN ISOPHANE BOVINE

Authority required

Diabetes mellitus

Clinical criteria:

Patient must be intolerant to human insulin.

insulin isophane bovine 100 units/mL injection, 1 x 10 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1711C NP	5	2	..	*374.13	38.30	Hypurin Isophane [AS]

▪ INSULIN ISOPHANE HUMAN

insulin isophane human 100 units/mL injection, 1 x 10 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1533Q NP	5	2	..	*120.43	38.30	Humulin NPH [LY]	Protaphane [NO]

insulin isophane human 100 units/mL injection, 5 x 3 mL cartridges

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1761Q NP	5	1	..	*200.68	38.30	Humulin NPH [LY] Protaphane Penfill 3 mL [NO]	Protaphane InnoLet [NI]

Insulins and analogues for injection, intermediate- or long-acting combined with fast-acting

▪ INSULIN ASPART + INSULIN ASPART PROTAMINE

insulin aspart 30 units/mL + insulin aspart protamine 70 units/mL injection, 5 x 3 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8609D NP	5	1	..	*239.93	38.30	NovoMix 30 FlexPen [NF]	NovoMix 30 Penfill 3 mL [NO]

▪ INSULIN ISOPHANE HUMAN + INSULIN NEUTRAL HUMAN

insulin isophane human 70 units/mL + insulin neutral human 30 units/mL injection, 5 x 3 mL cartridges

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1763T NP	5	1	..	*200.68	38.30	Humulin 30/70 [LY] Mixtard 30/70 Penfill 3 mL [NO]	Mixtard 30/70 InnoLet [NI]

insulin neutral human 30 units/mL + insulin isophane human 70 units/mL injection, 1 x 10 mL vial

1426C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	5	2	..	*120.43	38.30	Humulin 30/70 [LY]

insulin neutral human 50 units/mL + insulin isophane human 50 units/mL injection, 5 x 3 mL cartridges

2062M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	5	1	..	*200.68	38.30	Mixtard 50/50 Penfill 3 mL [NO]

▪ INSULIN LISPRO + INSULIN LISPRO PROTAMINE

insulin lispro 25 units/mL + insulin lispro protamine 75 units/mL injection, 5 x 3 mL cartridges

8390N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*239.93	38.30	Humalog Mix25 [LY]	Humalog Mix25 KwikPen [KP]

insulin lispro 50 units/mL + insulin lispro protamine 50 units/mL injection, 5 x 3 mL cartridges

8874C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*239.93	38.30	Humalog Mix50 [LY]	Humalog Mix50 KwikPen [KP]

Insulins and analogues for injection, long-acting

▪ INSULIN DETEMIR

Restricted benefit

Type 1 diabetes

insulin detemir 100 units/mL injection, 5 x 3 mL cartridges

9040T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*384.98	38.30	Levemir FlexPen [NF]	Levemir Penfill [NO]

▪ INSULIN GLARGINE

insulin glargine 100 units/mL injection, 5 x 3 mL cartridges

9039R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*405.58	38.30	Lantus [SW]	Lantus SoloStar [AV]

BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS

Biguanides

▪ METFORMIN

metformin hydrochloride 1 g tablet, 90

8607B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.65	16.82	[a] APO-Metformin 1000 [TX]	[a] Chem mart Metformin 1000 [CH]
						[a] Diaformin 1000 [AF]	[a] Formet 1000 [RW]
						[a] Glucobete 1000 [DO]	[a] Metformin AN [EA]
						[a] Metformin-GA [ED]	[a] Metformin generichealth 1000 [GQ]
						[a] Metformin Ranbaxy 1000 [RA]	[a] Metformin Sandoz [SZ]
						[a] Pharmacor Metformin 1000 [CR]	[a] Terry White Chemists Metformin 1000 [TW]
			[B]3.84	19.49	16.82	[a] Diabex 1000 [AL]	

metformin hydrochloride 1 g tablet: modified release, 60

3439B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.23	16.40	[a] APO-Metformin XR 1000 [TX]	[a] Diaformin XR 1000 [AF]
			[B]3.85	19.08	16.40	[a] Diabex XR 1000 [AL]	

metformin hydrochloride 500 mg tablet, 100

2430X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.42	14.59	[a] APO-Metformin 500 [TX]	[a] Chem mart Metformin [CH]
						[a] Diaformin [AF]	[a] Formet Aspen 500 [RW]
						[a] Glucobete 500 [DO]	[a] Metformin 500 [CR]
						[a] Metformin AN [EA]	[a] Metformin-GA [ED]
						[a] Metformin generichealth [GQ]	[a] Metformin Ranbaxy [RA]
						[a] Metformin Sandoz [SZ]	[a] Terry White Chemists Metformin [TW]
			[B]3.85	17.27	14.59	[a] Diabex [AL]	

metformin hydrochloride 500 mg tablet: modified release, 120

9435N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.23	16.40	[a] APO-Metformin XR 500 [TX]	[a] Chem mart Metformin XR 500 [CH]
						[a] Diaformin XR [AF]	[a] Metex XR [RW]
						[a] Terry White Chemists Metformin XR 500 [TW]	
			[B]3.85	19.08	16.40	[a] Diabex XR [AL]	

metformin hydrochloride 850 mg tablet, 60

1801T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.42	14.59	[a] APO-Metformin 850 [TX]	[a] Chem mart Metformin [CH]
						[a] Diaformin 850 [AF]	[a] Formet Aspen 850 [RW]
						[a] Glucobete 850 [DO]	[a] Metformin 850 [CR]
						[a] Metformin AN [EA]	[a] Metformin-GA [ED]
						[a] Metformin generichealth [GQ]	[a] Metformin Ranbaxy [RA]
						[a] Metformin Sandoz [SZ]	[a] Terry White Chemists Metformin [TW]
			[B]0.49	13.91	14.59	[a] Glucophage [MQ]	
			[B]3.85	17.27	14.59	[a] Diabex 850 [AL]	

Sulfonylureas

▪ GLIBENCLAMIDE

Caution Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

glibenclamide 5 mg tablet, 100

2939Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	14.74	15.91	[a] Glimel [AF]
			[B]1.25	15.99	15.91	[a] Daonil [SW]

▪ GLICLAZIDE

Caution Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

gliclazide 30 mg tablet: modified release, 100

8535F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.45	17.62	[a] APO-Gliclazide MR [TX]	[a] Chem mart Gliclazide MR [CH]
						[a] Glyade MR [AF]	[a] Oziclide MR [RA]
						[a] Terry White Chemists Gliclazide MR [TW]	

gliclazide 60 mg tablet: modified release, 60

9302N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	17.66	18.83	[a] ARDIX GLICLAZIDE 60mg MR [RX]
			[B]1.95	19.61	18.83	[a] Diamicron 60mg MR [SE]

gliclazide 80 mg tablet, 100

2449X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.28	17.45	[a] Chem mart Gliclazide [CH]	[a] GenRx Gliclazide [GX]
						[a] Glyade [AF]	[a] Nidem [RW]
						[a] Terry White Chemists Gliclazide [TW]	

▪ GLIMEPIRIDE

Caution Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

glimepiride 1 mg tablet, 30

8450R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	11.52	12.69	[a] APO-Glimepiride [TX]	[a] Aylide 1 [AF]
						[a] Diapride 1 [RW]	[a] Dimirel [AV]
						[a] Glimepiride AN [EA]	[a] Glimepiride GA 1 [ED]
						[a] Glimepiride Sandoz [SZ]	
			[B]2.23	13.75	12.69	[a] Amaryl [SW]	

glimepiride 2 mg tablet, 30

8451T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.52	13.69	[a] APO-Glimepiride [TX]	[a] Aylide 2 [AF]
						[a] Diapride 2 [RW]	[a] Dimirel [AV]
						[a] Glimepiride AN [EA]	[a] Glimepiride GA 2 [ED]
						[a] Glimepiride Sandoz [SZ]	

			[B]2.18	14.70	13.69	[a] Amaryl [SW]	

glimepiride 3 mg tablet, 30

8533D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.09	14.26	[a] APO-Glimepiride [TX]	[a] Aylide 3 [AF]
						[a] Diapride 3 [RW]	[a] Dimirel [AV]
						[a] Glimepiride AN [EA]	[a] Glimepiride GA 3 [ED]
						[a] Glimepiride Sandoz [SZ]	
			[B]2.19	15.28	14.26	[a] Amaryl [SW]	

glimepiride 4 mg tablet, 30

8452W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.70	14.87	[a] APO-Glimepiride [TX]	[a] Aylide 4 [AF]
						[a] Diapride 4 [RW]	[a] Dimirel [AV]
						[a] Glimepiride AN [EA]	[a] Glimepiride GA 4 [ED]
						[a] Glimepiride Sandoz [SZ]	
			[B]2.19	15.89	14.87	[a] Amaryl [SW]	

▪ GLIPIZIDE

Caution Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

glipizide 5 mg tablet, 100

2440K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	17.24	18.41	[a] Melizide [AF]
			[B]7.51	24.75	18.41	[a] Minidiab [PF]

Combinations of oral blood glucose lowering drugs

▪ ALOGLIPTIN + METFORMIN

Note This fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

Authority required (STREAMLINED)

4423

Diabetes mellitus type 2

Clinical criteria:

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

Authority required (STREAMLINED)

4427

Diabetes mellitus type 2

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and alogliptin.

alogliptin 12.5 mg + metformin hydrochloride 1 g tablet, 56

10035E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	61.34	38.30	Nesina Met 12.5/1000 [TK]

alogliptin 12.5 mg + metformin hydrochloride 500 mg tablet, 56

10033C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	59.77	38.30	Nesina Met 12.5/500 [TK]

alogliptin 12.5 mg + metformin hydrochloride 850 mg tablet, 56

10032B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	60.89	38.30	Nesina Met 12.5/850 [TK]

▪ DAPAGLIFLOZIN + METFORMIN

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

Authority required (STREAMLINED)

5631

Diabetes mellitus type 2

Clinical criteria:

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

Note This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

Authority required (STREAMLINED)

5739

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and dapagliflozin.

Note This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

Authority required (STREAMLINED)

5798

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with a sulfonylurea, AND

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

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

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

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

Note This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

Note PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

Authority required (STREAMLINED)

5657

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with insulin, AND

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR

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

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

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

Note This fixed dose combination is not PBS-subsidised as initial therapy or for use in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

dapagliflozin 10 mg + metformin hydrochloride 1 g tablet: modified release, 28

10515K (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	59.28	38.30	Xigduo XR 10/1000 [AP]

dapagliflozin 10 mg + metformin hydrochloride 500 mg tablet: modified release, 28

10516L (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	58.44	38.30	Xigduo XR 10/500 [AP]

dapagliflozin 5 mg + metformin hydrochloride 1 g tablet: modified release, 56

10510E (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	60.85	38.30	Xigduo XR 5/1000 [AP]

▪ EMPAGLIFLOZIN + METFORMIN

Note A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

Note This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

Authority required (STREAMLINED)

5953

Diabetes mellitus type 2

Clinical criteria:

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60

10640B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	64.45	38.30	Jardiamet 12.5 mg/1000 mg [BY]

empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60

10639Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	62.76	38.30	Jardiamet 12.5 mg/500 mg [BY]

empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60

10649L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	64.45	38.30	Jardiamet 5 mg/1000 mg [BY]

empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60

10650M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	62.76	38.30	Jardiamet 5 mg/500 mg [BY]

▪ EMPAGLIFLOZIN + METFORMIN

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

Authority required (STREAMLINED)

5966

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and empagliflozin.

Note This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

Authority required (STREAMLINED)

5798

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with a sulfonylurea, AND

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

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

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

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

Note This fixed dose combination is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

Note PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

Authority required (STREAMLINED)

5657

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with insulin, AND

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR

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

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

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

Note This fixed dose combination is not PBS-subsidised as initial therapy or for use in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10677Y NP	1	5	..	64.45	38.30	Jardiamet 12.5 mg/1000 mg [BY]

empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10633P NP	1	5	..	62.76	38.30	Jardiamet 12.5 mg/500 mg [BY]

empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10627H NP	1	5	..	64.45	38.30	Jardiamet 5 mg/1000 mg [BY]

empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10626G NP	1	5	..	62.76	38.30	Jardiamet 5 mg/500 mg [BY]

▪ LINAGLIPTIN + METFORMIN

Note This fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

Authority required (STREAMLINED)

4423

Diabetes mellitus type 2

Clinical criteria:

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

Authority required (STREAMLINED)

4448

Diabetes mellitus type 2

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and linagliptin.

linagliptin 2.5 mg + metformin hydrochloride 1 g tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10044P NP	1	5	..	64.99	38.30	Trajentamet [BY]

linagliptin 2.5 mg + metformin hydrochloride 500 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10038H NP	1	5	..	63.30	38.30	Trajentamet [BY]

linagliptin 2.5 mg + metformin hydrochloride 850 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10045Q NP	1	5	..	64.50	38.30	Trajentamet [BY]

▪ METFORMIN + GLIBENCLAMIDE

Caution Sulfonylureas may cause hypoglycaemia, particularly in the elderly.

metformin hydrochloride 250 mg + glibenclamide 1.25 mg tablet, 90

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8838E NP	1	5	..	17.46	18.63	Glucovance 250mg/1.25mg [AL]

metformin hydrochloride 500 mg + glibenclamide 2.5 mg tablet, 90

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8810Q NP	1	5	..	18.03	19.20	Glucovance 500mg/2.5mg [AL]

metformin hydrochloride 500 mg + glibenclamide 5 mg tablet, 90

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8811R NP	1	5	..	19.34	20.51	Glucovance 500mg/5mg [AL]

▪ ROSIGLITAZONE + METFORMIN

Note This fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a glucagon-like peptide-1, an insulin or an SGLT2 inhibitor.

Authority required

Diabetes mellitus type 2

Clinical criteria:

Patient must have a contraindication to a sulfonylurea; OR

Patient must not have tolerated a sulfonylurea, AND

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

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

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

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

rosiglitazone 2 mg + metformin hydrochloride 1 g tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9060W NP	1	5	..	60.93	38.30	Avandamet [GK]

rosiglitazone 2 mg + metformin hydrochloride 500 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9059T NP	1	5	..	59.36	38.30	Avandamet [GK]

rosiglitazone 4 mg + metformin hydrochloride 1 g tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9062Y NP	1	5	..	86.37	38.30	Avandamet [GK]

rosiglitazone 4 mg + metformin hydrochloride 500 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9061X NP	1	5	..	84.80	38.30	Avandamet [GK]

▪ SAXAGLIPTIN + METFORMIN

Note This fixed dose combination tablet is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor

Authority required (STREAMLINED)

5761

Diabetes mellitus type 2

Clinical criteria:

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

Authority required (STREAMLINED)

5762

Diabetes mellitus type 2

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and saxagliptin.

Authority required (STREAMLINED)

5705

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with a sulfonylurea, AND

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

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

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

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

Note PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

saxagliptin 2.5 mg + metformin hydrochloride 1 g tablet: modified release, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10048W NP	1	5	..	61.34	38.30	Kombiglyze XR 2.5/1000 [AP]

saxagliptin 5 mg + metformin hydrochloride 1 g tablet: modified release, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10051B NP	1	5	..	59.77	38.30	Kombiglyze XR 5/1000 [AP]

saxagliptin 5 mg + metformin hydrochloride 500 mg tablet: modified release, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10055F NP	1	5	..	58.93	38.30	Kombiglyze XR 5/500 [AP]

▪ SITAGLIPTIN + METFORMIN

Note This fixed dose combination tablet is not PBS-subsidised for use as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor

Authority required (STREAMLINED)

5761

Diabetes mellitus type 2

Clinical criteria:

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

Authority required (STREAMLINED)

5709

Diabetes mellitus type 2

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and sitagliptin.

Authority required (STREAMLINED)

5705

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with a sulfonylurea, AND

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

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

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

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

Note PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28

10089B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	57.38	38.30	Janumet XR [MK]

sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56

9451K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	58.95	38.30	Janumet [MK]

sitagliptin 50 mg + metformin hydrochloride 1 g tablet: modified release, 56

10090C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	58.95	38.30	Janumet XR [MK]

sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56

9449H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	57.38	38.30	Janumet [MK]

sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56

9450J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	58.50	38.30	Janumet [MK]

▪ VILDAGLIPTIN + METFORMIN

Note This fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

Authority required (STREAMLINED)

4423

Diabetes mellitus type 2

Clinical criteria:

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with metformin; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

A patient whose diabetes was previously demonstrated unable to be controlled with metformin does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination.

Authority required (STREAMLINED)

4308

Diabetes mellitus type 2

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and vildagliptin.

vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60

5476F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	59.63	38.30	Galvumet 50/1000 [NV]

vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60

5474D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	57.94	38.30	Galvumet 50/500 [NV]

vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60

5475E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	59.15	38.30	Galvumet 50/850 [NV]

Alpha glucosidase inhibitors

▪ ACARBOSE

acarbose 100 mg tablet, 90

8189B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	38.04	38.30	[a] Acarbose Mylan [AF]	[a] Glucobay 100 [BN]

acarbose 50 mg tablet, 90

8188Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	29.92	31.09	[a] Acarbose Mylan [AF]	[a] Glucobay 50 [BN]

Thiazolidinediones

▪ PIOGLITAZONE

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a glucagon-like peptide-1 or an SGLT2 inhibitor.

Authority required (STREAMLINED)

4363

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea, AND

Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR

Patient must not have tolerated a combination of metformin and a sulfonylurea, AND

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

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

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

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

Authority required (STREAMLINED)

4388

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with insulin, AND

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR

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

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

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

Authority required (STREAMLINED)

4364

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin, AND

The treatment must be in combination with a sulfonylurea, AND

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

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

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

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

pioglitazone 15 mg tablet, 28

8694N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	23.29	24.46	[a] Acpio 15 [RF] [a] Actos [TK] [a] Chem mart Pioglitazone [CH] [a] Pioglitazone AN [EA] [a] Pioglitazone Sandoz [SZ] [a] Prioten 15 [DO] [a] Vexazone [AF]	[a] Actaze [RW] [a] APOTEX-Pioglitazone [TX] [a] Pharmacor Pioglitazone 15 [CR] [a] Pioglitazone-GA [ED] [a] Pizaccord [RA] [a] Terry White Chemists Pioglitazone [TW]

pioglitazone 30 mg tablet, 28

8695P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	30.21	31.38	[a] Acpio 30 [RF] [a] Actos [TK] [a] Chem mart Pioglitazone [CH] [a] Pioglitazone AN [EA] [a] Pioglitazone Sandoz [SZ] [a] Prioten 30 [DO] [a] Vexazone [AF]	[a] Actaze [RW] [a] APOTEX-Pioglitazone [TX] [a] Pharmacor Pioglitazone 30 [CR] [a] Pioglitazone-GA [ED] [a] Pizaccord [RA] [a] Terry White Chemists Pioglitazone [TW]

pioglitazone 45 mg tablet, 28

8696Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	36.15	37.32	[a] Acpio 45 [RF] [a] Actos [TK] [a] Chem mart Pioglitazone [CH] [a] Pioglitazone AN [EA] [a] Pioglitazone Sandoz [SZ] [a] Prioten 45 [DO] [a] Vexazone [AF]	[a] Actaze [RW] [a] APOTEX-Pioglitazone [TX] [a] Pharmacor Pioglitazone 45 [CR] [a] Pioglitazone-GA [ED] [a] Pizaccord [RA] [a] Terry White Chemists Pioglitazone [TW]

▪ ROSIGLITAZONE

Note This drug is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a glucagon-like peptide-1, an insulin or an SGLT2 inhibitor.

Authority required

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea, AND

Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR

Patient must not have tolerated a combination of metformin and a sulfonylurea, AND

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

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

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

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

rosiglitazone 4 mg tablet, 28

8689H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	57.69	38.30	Avandia [GK]

rosiglitazone 8 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8690J NP	1	5	..	83.13	38.30	Avandia [GK]

Dipeptidyl peptidase 4 (DPP-4) inhibitors

▪ ALOGLIPTIN

Note Alogliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

Authority required (STREAMLINED)

4349

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea, AND

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with alogliptin.

alogliptin 12.5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2933J NP	1	5	..	58.09	38.30	Nesina [TK]

alogliptin 25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2986E NP	1	5	..	58.09	38.30	Nesina [TK]

alogliptin 6.25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2944Y NP	1	5	..	58.09	38.30	Nesina [TK]

▪ LINAGLIPTIN

Note Linagliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

Authority required (STREAMLINED)

4488

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea, AND

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with linagliptin.

linagliptin 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3387G NP	1	5	..	61.50	38.30	Trajenta [BY]

▪ SAXAGLIPTIN

Authority required (STREAMLINED)

5623

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea, AND

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with saxagliptin.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

Authority required (STREAMLINED)

5679

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin, AND

The treatment must be in combination with a sulfonylurea, AND

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

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

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

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

Note PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

saxagliptin 2.5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10128C NP	1	5	..	58.09	38.30	Onglyza [AP]

saxagliptin 5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8983T NP	1	5	..	58.09	38.30	Onglyza [AP]

▪ SITAGLIPTIN

Authority required (STREAMLINED)

5655

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea, AND

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with sitagliptin.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

Authority required (STREAMLINED)

5679

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin, AND

The treatment must be in combination with a sulfonylurea, AND

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

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

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

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

Note PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

sitagliptin 100 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9182G NP	1	5	..	55.71	38.30	Januvia [MK]

sitagliptin 25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9180E NP	1	5	..	55.71	38.30	Januvia [MK]

sitagliptin 50 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9181F NP	1	5	..	55.71	38.30	Januvia [MK]

▪ VILDAGLIPTIN

Note Vildagliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

Authority required (STREAMLINED)

4467

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea, AND

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with vildagliptin.

vildagliptin 50 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3415R NP	1	5	..	58.94	38.30	Galvus [NV]

Other blood glucose lowering drugs, excl. insulins

▪ DAPAGLIFLOZIN

Note Continuing Therapy Only:

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

Note This drug is not PBS subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

Authority required (STREAMLINED)

4983

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea, AND

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

Authority required (STREAMLINED)

4991

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with insulin, AND

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR

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

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

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

Authority required (STREAMLINED)

5629

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin, AND

The treatment must be in combination with a sulfonylurea, AND

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

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

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

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

Note PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

dapagliflozin 10 mg tablet, 28

10011X NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	57.60	38.30	Forxiga [AP]

▪ EMPAGLIFLOZIN

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

Note This drug is not PBS subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

Authority required (STREAMLINED)

5629

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin, AND

The treatment must be in combination with a sulfonylurea, AND

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

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

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

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

Note PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

Authority required (STREAMLINED)

4983

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea, AND

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug.

Authority required (STREAMLINED)

4991

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with insulin, AND

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR

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

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

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

empagliflozin 10 mg tablet, 30

10206E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	60.97	38.30	Jardiance [BY]

NP

empagliflozin 25 mg tablet, 30

10202Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	60.97	38.30	Jardiance [BY]

▪ EXENATIDE

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or an SGLT2 inhibitor.

Authority required (STREAMLINED)

5500

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea, AND

Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR

Patient must not have tolerated a combination of metformin and a sulfonylurea, AND

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

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

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

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

Authority required (STREAMLINED)

5478

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin, AND

The treatment must be in combination with a sulfonylurea, AND

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

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

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

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

Authority required (STREAMLINED)

5469

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with insulin, AND

The treatment must be in combination with metformin unless contraindicated or not tolerated, AND

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR

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

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

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

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

(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or

(b) Had red cell transfusion within the previous 3 months.

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

exenatide 10 microgram/0.04 mL injection, 60 x 0.04 mL unit doses

3424F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	88.87	38.30	Byetta 10 microgram [AP]

exenatide 5 microgram/0.02 mL injection, 60 x 0.02 mL unit doses

3423E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	65.33	38.30	Byetta 5 microgram [AP]

▪ VITAMINS

VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO

Vitamin D and analogues

▪ CALCITRIOL

Authority required (STREAMLINED)

5401

Hypocalcaemia

Clinical criteria:

The condition must be due to renal disease.

Authority required (STREAMLINED)

5255

Hypoparathyroidism

Authority required (STREAMLINED)

5089

Hypophosphataemic rickets

Authority required (STREAMLINED)

5114

Vitamin D-resistant rickets

Authority required (STREAMLINED)

5402

Established osteoporosis

Clinical criteria:

Patient must have fracture due to minimal trauma.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

calcitriol 0.25 microgram capsule, 100

2502Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	28.83	30.00	[a] APO-Calcitriol [TX] [a] Calcitriol AN [EA] [a] Calcitriol Sandoz [SZ] [a] Kosteo [RW] [a] Sical [AF]	[a] Calciprox [ER] [a] Calcitriol-GA [ED] [a] GenRx Calcitriol [GX] [a] Rocaltrol [RO]

VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12

Vitamin B1, plain

▪ THIAMINE

Authority required (STREAMLINED)

5139

Thiamine deficiency

Clinical criteria:

The treatment must be for prophylaxis.

Population criteria:

Patient must be an Aboriginal or a Torres Strait Islander person.

thiamine hydrochloride 100 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1070H NP	1	2	..	13.47	14.64	Betavit [PP]

MINERAL SUPPLEMENTS

CALCIUM

Calcium

CALCIUM

Authority required (STREAMLINED)

4586

Hyperphosphataemia

Clinical criteria:

The condition must be associated with chronic renal failure.

CALCIUM Tablet (chewable) 500 mg (as carbonate), 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3116B NP	4	1	..	*28.97	30.14	[a] Cal-500 [PP]	[a] Cal-Sup [IA]

CALCIUM Tablet 600 mg (as carbonate), 240

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3117C NP	1	1	..	23.45	24.62	Calci-Tab 600 [AE]

POTASSIUM

Potassium

POTASSIUM CHLORIDE

Note For item codes 2642C and 1841X, pharmaceutical benefits that have the form tablet 600 mg (sustained release) are equivalent for the purposes of substitution.

potassium chloride 600 mg (potassium 8 mmol) tablet: modified release, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2642C NP	2	1	..	*18.61	19.78	[a] Duro-K [NM]	[a] Slow-K [NV]

potassium chloride 600 mg (potassium 8 mmol) tablet: modified release, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1841X NP	1	1	..	18.59	19.76	[a] Span-K [AS]

POTASSIUM CHLORIDE + POTASSIUM BICARBONATE + POTASSIUM CARBONATE

potassium chloride 595 mg + potassium bicarbonate 384 mg + potassium carbonate 152 mg tablet: effervescent, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3012M NP	1	1	..	18.00	19.17	Chlorvescent [AS]

OTHER MINERAL SUPPLEMENTS

Magnesium

MAGNESIUM ASPARTATE DIHYDRATE

Authority required (STREAMLINED)

5506

Hypomagnesaemia

Population criteria:

Patient must be an Aboriginal or a Torres Strait Islander person.

Authority required (STREAMLINED)

5466

Chronic renal disease

Population criteria:

Patient must be an Aboriginal or a Torres Strait Islander person.

magnesium aspartate dihydrate 500 mg (equivalent to 37.4 mg of magnesium) tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5146W NP	1	5	..	16.75	17.92	MagMin (PBS) [BB]	Mag-Sup [PP]

ANABOLIC AGENTS FOR SYSTEMIC USE

ANABOLIC STEROIDS

Estren derivatives

NANDROLONE DECANOATE

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

Authority required
Osteoporosis
Clinical criteria:
The treatment must be as monotherapy, AND
The treatment must be where other treatment has failed and where specialist advice confirms that this is the only suitable treatment option for the patient.
Specialist advice need only be obtained for the first authority approval.

Authority required
Osteoporosis
Clinical criteria:
The treatment must be as monotherapy, AND
The treatment must be where other treatment is not tolerated and where specialist advice confirms that this is the only suitable treatment option for the patient.
Specialist advice need only be obtained for the first authority approval.

Authority required
Osteoporosis
Clinical criteria:
The treatment must be as monotherapy, AND
The treatment must be where other treatment is contraindicated and where specialist advice confirms that this is the only suitable treatment option for the patient.
Specialist advice need only be obtained for the first authority approval.

Authority required
Patients receiving this drug as a pharmaceutical benefit prior to 1 February 2004

Authority required
Patients on long-term treatment with corticosteroids

nandrolone decanoate 50 mg/mL injection, 1 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1671Y	1	7	..	22.62	23.79	Deca-Durabolin [AS]

OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

Amino acids and derivatives

BETAINE

Authority required
Homocystinuria
Clinical criteria:
The treatment must be as adjunctive therapy to current standard care, AND
The condition must be treated by or in consultation with a metabolic physician.
The name of the specialist must be included in the authority application.

betaine 1 g/g oral liquid: powder for, 180 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10119N	‡1	5	..	565.20	38.30	Cystadane [EU]

Various alimentary tract and metabolism products

SAPROPTERIN

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Hyperphenylalaninaemia

Treatment Phase: Continuing

Clinical criteria:

Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency, AND

Patient must have previously been issued with an authority prescription for this drug; OR

Patient must have accessed non-PBS-subsidised treatment prior to 1 May 2014.

Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

The authority application must be made in writing.

sapropterin dihydrochloride 100 mg tablet: soluble, 30

10087X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
6	5	..	*5306.91	38.30	Kuvan [IO]

▪ SAPROPTERIN

Note Patients will be eligible for a maximum of one script as initial therapy to enable their response to treatment with sapropterin to be assessed.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Hyperphenylalaninaemia

Treatment Phase: Initial

Clinical criteria:

Patient must have hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency.

Patient must have documented tetrahydrobiopterin (BH4) deficiency using tests for BH4 loading and/or urine pterin metabolites, blood spot dihydropteridine reductase (DHPR) and have cerebrospinal fluid neurotransmitter metabolites measured.

The authority application must be made in writing.

sapropterin dihydrochloride 100 mg tablet: soluble, 30

10086W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
6	..	..	*5306.91	38.30	Kuvan [IO]

▪ BLOOD AND BLOOD FORMING ORGANS

▪ ANTITHROMBOTIC AGENTS

ANTITHROMBOTIC AGENTS

Vitamin K antagonists

▪ WARFARIN

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

warfarin sodium 1 mg tablet, 50

2843P (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	15.38	16.55	Coumadin [QA]	Marevan [FM]

warfarin sodium 2 mg tablet, 50

2209G (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	15.66	16.83	Coumadin [QA]

warfarin sodium 3 mg tablet, 50

2844Q (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	15.60	16.77	Marevan [FM]

warfarin sodium 5 mg tablet, 50

2211J (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	16.71	17.88	Coumadin [QA]	Marevan [FM]

Heparin group

▪ DALTEPARIN SODIUM

dalteparin sodium 10 000 anti-Xa units/mL injection, 10 x 1 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8269F NP	1	1	..	83.46	38.30	Fragmin [PF]

dalteparin sodium 12 500 anti-Xa units/0.5 mL injection, 10 x 0.5 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5445N NP	1	1	..	113.43	38.30	Fragmin [PF]

dalteparin sodium 2500 anti-Xa units/0.2 mL injection, 10 x 0.2 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8603T NP	2	..	..	*95.33	38.30	Fragmin [PF]

dalteparin sodium 5000 anti-Xa units/0.2 mL injection, 10 x 0.2 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2816F NP	2	..	..	*98.89	38.30	Fragmin [PF]

dalteparin sodium 7500 anti-Xa units/0.75 mL injection, 10 x 0.75 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8271H NP	1	1	..	63.93	38.30	Fragmin [PF]

▪ DALTEPARIN SODIUM

Restricted benefit

Haemodialysis

dalteparin sodium 10 000 anti-Xa units/mL injection, 10 x 1 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1229Q NP	2	3	..	*156.51	38.30	Fragmin [PF]

dalteparin sodium 12 500 anti-Xa units/0.5 mL injection, 10 x 0.5 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1296F NP	2	3	..	*217.35	38.30	Fragmin [PF]

dalteparin sodium 2500 anti-Xa units/0.2 mL injection, 10 x 0.2 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8641T NP	2	3	..	*95.33	38.30	Fragmin [PF]

dalteparin sodium 5000 anti-Xa units/0.2 mL injection, 10 x 0.2 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8642W NP	2	3	..	*98.89	38.30	Fragmin [PF]

dalteparin sodium 7500 anti-Xa units/0.75 mL injection, 10 x 0.75 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8643X NP	2	3	..	*117.45	38.30	Fragmin [PF]

▪ DALTEPARIN SODIUM

Note No applications for increased maximum quantities will be authorised.

Restricted benefit

Symptomatic venous thromboembolism
Treatment Phase: Management
Clinical criteria:
Patient must have a solid tumour(s).

DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium-porcine mucous) Injection 15,000 units (anti-Xa) in 0.6 mL single dose pre-filled syringe, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8959M NP	3	5	..	*387.90	38.30	Fragmin [PF]

DALTEPARIN SODIUM (Low Molecular Weight Heparin Sodium-porcine mucous) Injection 18,000 units (anti-Xa) in 0.72 mL single dose pre-filled syringe, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8960N NP	3	5	..	*464.67	38.30	Fragmin [PF]

dalteparin sodium 10 000 anti-Xa units/mL injection, 10 x 1 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8957K NP	3	5	..	*230.91	38.30	Fragmin [PF]

dalteparin sodium 12 500 anti-Xa units/0.5 mL injection, 10 x 0.5 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8958L NP	3	5	..	*323.97	38.30	Fragmin [PF]

dalteparin sodium 7500 anti-Xa units/0.75 mL injection, 10 x 0.75 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8956J NP	3	5	..	*170.94	38.30	Fragmin [PF]

▪ ENOXAPARIN SODIUM

enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8264Y NP	1	1	..	99.08	38.30	Clexane [SW]

enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8558K NP	2	..	..	*95.33	38.30	Clexane [SW]

enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8510X NP	2	..	..	*98.89	38.30	Clexane [SW]

enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8262W NP	1	1	..	73.68	38.30	Clexane [SW]

enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8263X NP	1	1	..	83.21	38.30	Clexane [SW]

▪ ENOXAPARIN SODIUM

Restricted benefit

Haemodialysis

enoxaparin sodium 100 mg/mL injection, 10 x 1 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5435C NP	2	3	..	*187.75	38.30	Clexane [SW]

enoxaparin sodium 20 mg/0.2 mL injection, 10 x 0.2 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8716R NP	2	3	..	*95.33	38.30	Clexane [SW]

enoxaparin sodium 40 mg/0.4 mL injection, 10 x 0.4 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8639Q NP	2	3	..	*98.89	38.30	Clexane [SW]

enoxaparin sodium 60 mg/0.6 mL injection, 10 x 0.6 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8640R NP	2	3	..	*136.95	38.30	Clexane [SW]

enoxaparin sodium 80 mg/0.8 mL injection, 10 x 0.8 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5434B NP	2	3	..	*156.01	38.30	Clexane [SW]

▪ HEPARIN SODIUM

heparin sodium 35 000 units/35 mL injection, 35 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1076P NP	12	5	..	*353.97	38.30	Hospira Pty Limited [HH]

heparin sodium 5000 units/0.2 mL injection, 5 x 0.2 mL ampoules

1466E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	23.09	24.26	Hospira Pty Limited [HH]

heparin sodium 5000 units/5 mL injection, 50 x 5 mL ampoules

1463B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	72.02	38.30	Pfizer Australia Pty Ltd [PF]

▪ NADROPARIN

nadroparin calcium 11 400 anti-Xa international units/0.6 mL injection, 2 x 0.6 mL syringes

10706L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	1	..	31.87	33.04	Fraxiparine Forte [AS]

nadroparin calcium 15 200 anti-Xa international units/0.8 mL injection, 2 x 0.8 mL syringes

10725L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	1	..	39.02	38.30	Fraxiparine Forte [AS]

nadroparin calcium 19 000 anti-Xa international units/mL injection, 2 x 1 mL syringes

10707M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	1	..	46.17	38.30	Fraxiparine Forte [AS]

nadroparin calcium 1900 anti-Xa international units/0.2 mL injection, 2 x 0.2 mL syringes

10735B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*17.59	18.76	Fraxiparine [AS]

nadroparin calcium 2850 anti-Xa international units/0.3 mL injection, 2 x 0.3 mL syringes

10686K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*21.17	22.34	Fraxiparine [AS]

nadroparin calcium 3800 anti-Xa international units/0.4 mL injection, 2 x 0.4 mL syringes

10685J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*24.73	25.90	Fraxiparine [AS]

nadroparin calcium 5700 anti-Xa international units/0.6 mL injection, 2 x 0.6 mL syringes

10716B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*31.89	33.06	Fraxiparine [AS]

nadroparin calcium 7600 anti-Xa international units/0.8 mL injection, 2 x 0.8 mL syringes

10734Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	1	..	24.72	25.89	Fraxiparine [AS]

nadroparin calcium 9500 anti-Xa international units/mL injection, 2 x 1 mL syringes

10702G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	1	..	28.30	29.47	Fraxiparine [AS]

▪ NADROPARIN

Restricted benefit
Haemodialysis

nadroparin calcium 1900 anti-Xa international units/0.2 mL injection, 2 x 0.2 mL syringes

10687L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	3	..	*17.59	18.76	Fraxiparine [AS]

nadroparin calcium 2850 anti-Xa international units/0.3 mL injection, 2 x 0.3 mL syringes

10701F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	3	..	*21.17	22.34	Fraxiparine [AS]

nadroparin calcium 3800 anti-Xa international units/0.4 mL injection, 2 x 0.4 mL syringes

10717C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	3	..	*24.73	25.90	Fraxiparine [AS]

nadroparin calcium 5700 anti-Xa international units/0.6 mL injection, 2 x 0.6 mL syringes

10718D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	3	..	*31.89	33.06	Fraxiparine [AS]

nadroparin calcium 7600 anti-Xa international units/0.8 mL injection, 2 x 0.8 mL syringes

10740G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	3	..	*39.03	38.30	Fraxiparine [AS]

nadroparin calcium 9500 anti-Xa international units/mL injection, 2 x 1 mL syringes

10733X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	3	..	*46.19	38.30	Fraxiparine [AS]

Platelet aggregation inhibitors excl. heparin

▪ ABCIXIMAB

Authority required (STREAMLINED)

4942

Coronary artery disease

Treatment criteria:

Patient must be undergoing percutaneous coronary balloon angioplasty.

Authority required (STREAMLINED)

4943

Coronary artery disease

Treatment criteria:

Patient must be undergoing percutaneous coronary atherectomy.

Authority required (STREAMLINED)

4915

Coronary artery disease

Treatment criteria:

Patient must be undergoing percutaneous coronary stent placement.

abciximab 10 mg/5 mL injection, 5 mL vial

8048N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	3	..	..	*1375.47	38.30	ReoPro [LY]

▪ ASPIRIN

Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

aspirin 300 mg tablet: effervescent, 96

1010E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	1	..	11.94	13.11	Solprin [RC]

▪ ASPIRIN

Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

aspirin 100 mg tablet, 112

8202Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	1	..	11.68	12.85	Spren 100 [QA]

▪ CLOPIDOGREL

Note Not for prophylaxis of deep vein thrombosis or peripheral arterial disease.

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

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

Authority required (STREAMLINED)

4166

Acute coronary syndrome (myocardial infarction or unstable angina)

Clinical criteria:

The treatment must be in combination with aspirin.

Authority required (STREAMLINED)

4165

Cardiac stent insertion

Clinical criteria:
The treatment must be in combination with aspirin, AND
The treatment must follow insertion of a cardiac stent.

clopidogrel 75 mg tablet, 28

2275R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.38	17.55	[a] Clopidogrel-GA [EA] [a] Plidogrel [RF]	[a] Clovix 75 [RW]

clopidogrel 75 mg tablet, 28

9317J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.38	17.55	[a] APO-Clopidogrel [TX] [a] Chem mart Clopidogrel [CH] [a] Clopidogrel Winthrop [WA] [a] Piax [AF] [a] Terry White Chemists Clopidogrel [TW]	[a] Blooms the Chemist Clopidogrel [IB] [a] Clopidogrel AN [EA] [a] Iscover [AV] [a] Plavix [SW]

▪ CLOPIDOGREL

Note Not for prophylaxis of deep vein thrombosis or peripheral arterial disease.

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

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

Authority required (STREAMLINED)
5517
Prevention of recurrence of myocardial infarction or unstable angina
Clinical criteria:
Patient must have a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin.

Authority required (STREAMLINED)
5524
Prevention of recurrence of myocardial infarction or unstable angina
Clinical criteria:
Patient must be in one whom low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding.

Authority required (STREAMLINED)
5525
Prevention of recurrence of myocardial infarction or unstable angina
Clinical criteria:
Patient must have a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or non-steroidal anti-inflammatory drugs (NSAIDs).

Authority required (STREAMLINED)
5459
Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events
Clinical criteria:
Patient must have a history of symptomatic cerebrovascular ischaemic episodes while on therapy with low-dose aspirin.

Authority required (STREAMLINED)
5436
Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events
Clinical criteria:
Patient must be in one whom low-dose aspirin poses an unacceptable risk of gastrointestinal bleeding.

Authority required (STREAMLINED)
5508
Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events
Clinical criteria:
Patient must have a history of anaphylaxis, urticaria or asthma within 4 hours of ingestion of aspirin, other salicylates, or non-steroidal anti-inflammatory drugs (NSAIDs).

clopidogrel 75 mg tablet, 28

5436D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	16.38	17.55	[a] Clopidogrel-DRLA [RZ]

clopidogrel 75 mg tablet, 28

8358X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.38	17.55	[a] APO-Clopidogrel [TX]	[a] Blooms the Chemist Clopidogrel [IB]

						[a] Chem mart Clopidogrel [CH] [a] Clopidogrel RBX [RA] [a] Clopidogrel Winthrop [WA] [a] Piax [AF] [a] Plavix [SW]	[a] Clopidogrel AN [EA] [a] Clopidogrel Sandoz [SZ] [a] Iscover [AV] [a] Plavicor 75 [CR] [a] Terry White Chemists Clopidogrel [TW]

clopidogrel 75 mg tablet, 28

9354H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.38	17.55	[a] Clopidogrel-GA [EA] [a] Clovix 75 [RW]	[a] Clopidogrel GH [GQ] [a] Plidogrel [RF]

▪ CLOPIDOGREL + ASPIRIN

Note Not for prophylaxis of deep vein thrombosis or peripheral arterial disease.

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

Authority required (STREAMLINED)

5488

Acute coronary syndrome (myocardial infarction or unstable angina)

Authority required (STREAMLINED)

5443

Cardiac stent insertion

Clinical criteria:

The treatment must follow insertion of a cardiac stent.

Authority required (STREAMLINED)

5517

Prevention of recurrence of myocardial infarction or unstable angina

Clinical criteria:

Patient must have a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin.

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

clopidogrel 75 mg + aspirin 100 mg tablet, 30

9296G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.81	17.98	[a] APO-Clopidogrel/Aspirin 75/100 [TX] [a] Clopidogrel/Aspirin Actavis 75/100 [EA] [a] Clopidogrel Winthrop plus aspirin [WA] [a] DuoCover [AV] [a] Piax Plus Aspirin [AF]	[a] Chem mart Clopidogrel/Aspirin 75/100 [CH] [a] Clopidogrel/Aspirin Sandoz 75/100 [SZ] [a] CoPlavix [SW] [a] DuoPlidogrel [GZ] [a] Terry White Chemists Clopidogrel/Aspirin 75/100 [TW]

▪ DIPYRIDAMOLE

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

Restricted benefit

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events as adjunctive therapy with low-dose aspirin

Restricted benefit

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

Restricted benefit

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

dipyridamole 200 mg capsule: modified release, 60

8335Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	35.65	36.82	Persantin SR [BY]

▪ DIPYRIDAMOLE + ASPIRIN

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Prevention of recurrence of ischaemic stroke or transient cerebral ischaemic events

dipyridamole 200 mg + aspirin 25 mg capsule: modified release, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8382E NP	1	5	..	32.90	34.07	[a] APO-Dipyridamole/Aspirin 200/25 [TX] [a] Diasp SR [RW]	[a] Asasantin SR [BY]

▪ EPTIFIBATIDE

Authority required (STREAMLINED)

1884

Patients undergoing non-urgent percutaneous intervention with intracoronary stenting

eptifibatide 20 mg/10 mL injection, 10 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8683B	2	..	..	*238.23	38.30	Integrilin [MK]

eptifibatide 75 mg/100 mL injection, 100 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8684C	3	..	..	*962.73	38.30	Integrilin [MK]

▪ PRASUGREL

Note Shared Care Model:

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

Authority required (STREAMLINED)

3208

Treatment of acute coronary syndrome (myocardial infarction or unstable angina) managed by percutaneous coronary intervention in combination with aspirin

prasugrel 10 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9496T NP	1	5	..	96.79	38.30	Effient [LY]

prasugrel 5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9495R NP	1	5	..	88.16	38.30	Effient [LY]

▪ TICAGRELOR

Note Shared Care Model:

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

Authority required (STREAMLINED)

5746

Acute coronary syndrome (myocardial infarction or unstable angina)

Clinical criteria:

The treatment must be in combination with aspirin.

TICAGRELOR Tablet 90 mg, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1418P NP	1	5	..	140.04	38.30	Brilinta [AP]

▪ TIROFIBAN

Note Shared Care Model:

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

Authority required (STREAMLINED)

5782

High risk of unstable angina

Clinical criteria:

Patient must have new transient or persistent ST-T ischaemic changes, AND

Patient must have pain lasting longer than 20 minutes.

Authority required (STREAMLINED)

5809

High risk of unstable angina

Clinical criteria:

Patient must have new transient or persistent ST-T ischaemic changes, AND

Patient must have repetitive episodes of angina at rest or during minimal exercise in the previous 12 hours.

Authority required (STREAMLINED)

5691

Non-Q-wave myocardial infarction

tirofiban 12.5 mg/50 mL injection, 50 mL vial

8350L (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	298.58	38.30	[a] Aggrastat [AS]	[a] Tirofiban AC [JO]

Enzymes

▪ RETEPLASE

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

Restricted benefit

Acute myocardial infarction

Clinical criteria:

The treatment must be administered within 6 hours of the onset of attack.

reteplase 10 units (17.4 mg) injection [2 x 10 unit vials] (&) inert substance diluent [2 x 10 mL syringes], 1 pack

8253J (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	1964.94	38.30	Rapilysin 10 U [GN]

▪ TENECTEPLASE

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

Restricted benefit

Acute myocardial infarction

Clinical criteria:

The treatment must be administrated within 12 hours of onset of attack.

tenecteplase 10 000 units (50 mg) injection [1 vial] (&) inert substance diluent [10 mL syringe], 1 pack

8527T (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	1955.21	38.30	Metalyse [BY]

tenecteplase 8000 units (40 mg) injection [1 vial] (&) inert substance diluent [8 mL syringe], 1 pack

8526R (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	1860.52	38.30	Metalyse [BY]

Direct thrombin inhibitors

▪ BIVALIRUDIN

Authority required (STREAMLINED)

4919

Coronary artery disease

Treatment criteria:

Patient must be undergoing percutaneous coronary intervention.

bivalirudin 250 mg injection, 1 vial

8844L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	633.15	38.30	Angiomax [XM]

▪ DABIGATRAN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

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

Authority required (STREAMLINED)

4402

Prevention of venous thromboembolism

Clinical criteria:

Patient must require up to 30 days supply to complete a course of treatment.

Treatment criteria:

Patient must be undergoing total hip replacement.

dabigatran etexilate 110 mg capsule, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9321N NP	1	..	..	87.71	38.30	Pradaxa [BY]

dabigatran etexilate 75 mg capsule, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9320M NP	1	..	..	109.12	38.30	Pradaxa [BY]

▪ DABIGATRAN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

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

Authority required (STREAMLINED)

4369

Prevention of venous thromboembolism

Clinical criteria:

Patient must require up to 20 days supply to complete a course of treatment.

Treatment criteria:

Patient must be undergoing total hip replacement.

dabigatran etexilate 110 mg capsule, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9319L NP	2	1	..	*36.19	37.36	Pradaxa [BY]

dabigatran etexilate 75 mg capsule, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9318K NP	2	1	..	*43.33	38.30	Pradaxa [BY]

▪ DABIGATRAN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

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

Authority required (STREAMLINED)

4381

Prevention of venous thromboembolism

Clinical criteria:

Patient must require up to 10 days of therapy.

Treatment criteria:

Patient must be undergoing total knee replacement.

dabigatran etexilate 110 mg capsule, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9323Q NP	2	..	..	*36.19	37.36	Pradaxa [BY]

dabigatran etexilate 75 mg capsule, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9322P NP	2	..	..	*43.33	38.30	Pradaxa [BY]

▪ DABIGATRAN

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

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)
4269
Prevention of stroke or systemic embolism
Clinical criteria:
Patient must have non-valvular atrial fibrillation, AND
Patient must have one or more risk factors for developing stroke or systemic embolism.
Risk factors for developing stroke or systemic ischaemic embolism are:
(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
(ii) age 75 years or older;
(iii) hypertension;
(iv) diabetes mellitus;
(v) heart failure and/or left ventricular ejection fraction 35% or less.

dabigatran etexilate 110 mg capsule, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2753X NP	1	5	..	87.71	38.30	Pradaxa [BY]

dabigatran etexilate 150 mg capsule, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2769R NP	1	5	..	87.71	38.30	Pradaxa [BY]

Direct factor Xa inhibitors

▪ APIXABAN

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
4402
Prevention of venous thromboembolism
Clinical criteria:
Patient must require up to 30 days supply to complete a course of treatment.
Treatment criteria:
Patient must be undergoing total hip replacement.

apixaban 2.5 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5061J NP	1	..	..	96.58	38.30	Eliquis [BQ]

▪ APIXABAN

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)
4098
Deep vein thrombosis
Treatment Phase: Initial treatment
Clinical criteria:
Patient must have confirmed acute symptomatic deep vein thrombosis, AND
Patient must not have symptomatic pulmonary embolism.
Authority required (STREAMLINED)
5098
Pulmonary embolism
Treatment Phase: Initial treatment
Clinical criteria:
Patient must have confirmed acute symptomatic pulmonary embolism.

apixaban 5 mg tablets, 28

10414D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	50.62	38.30	Eliquis [BQ]

- **APIXABAN**

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
4382
Prevention of venous thromboembolism
Clinical criteria:
Patient must require up to 15 days of therapy.
Treatment criteria:
Patient must be undergoing total knee replacement.
Authority required (STREAMLINED)
4409
Prevention of venous thromboembolism
Clinical criteria:
Patient must require up to 15 days supply to complete a course of treatment.
Treatment criteria:
Patient must be undergoing total hip replacement.

apixaban 2.5 mg tablet, 30

5054B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	53.50	38.30	Eliquis [BQ]

- **APIXABAN**

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
4381
Prevention of venous thromboembolism
Clinical criteria:
Patient must require up to 10 days of therapy.
Treatment criteria:
Patient must be undergoing total knee replacement.
Authority required (STREAMLINED)
4359
Prevention of venous thromboembolism
Clinical criteria:
Patient must require up to 10 days supply to complete a course of treatment.
Treatment criteria:
Patient must be undergoing total hip replacement.

apixaban 2.5 mg tablet, 20

5500L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	39.14	38.30	Eliquis [BQ]

- **APIXABAN**

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)
4269
Prevention of stroke or systemic embolism

Clinical criteria:
Patient must have non-valvular atrial fibrillation, AND
Patient must have one or more risk factors for developing stroke or systemic embolism.
Risk factors for developing stroke or systemic ischaemic embolism are:
(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
(ii) age 75 years or older;
(iii) hypertension;
(iv) diabetes mellitus;
(v) heart failure and/or left ventricular ejection fraction 35% or less.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)
4132
Prevention of recurrent venous thromboembolism
Treatment Phase: Continuing treatment
Clinical criteria:
Patient must have a history of venous thromboembolism.

apixaban 2.5 mg tablet, 60

2744K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	96.58	38.30	Eliquis [BQ]

▪ APIXABAN

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

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)
4269
Prevention of stroke or systemic embolism
Clinical criteria:
Patient must have non-valvular atrial fibrillation, AND
Patient must have one or more risk factors for developing stroke or systemic embolism.
Risk factors for developing stroke or systemic ischaemic embolism are:
(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;
(ii) age 75 years or older;
(iii) hypertension;
(iv) diabetes mellitus;
(v) heart failure and/or left ventricular ejection fraction 35% or less.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)
4099
Deep vein thrombosis
Treatment Phase: Continuing treatment
Clinical criteria:
Patient must have confirmed acute symptomatic deep vein thrombosis, AND
Patient must not have symptomatic pulmonary embolism.

Authority required (STREAMLINED)
5083
Pulmonary embolism
Treatment Phase: Continuing treatment
Clinical criteria:
Patient must have confirmed acute symptomatic pulmonary embolism.

apixaban 5 mg tablet, 60

2735Y NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	96.57	38.30	Eliquis [BQ]

▪ RIVAROXABAN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4369

Prevention of venous thromboembolism

Clinical criteria:

Patient must require up to 20 days supply to complete a course of treatment.

Treatment criteria:

Patient must be undergoing total hip replacement.

rivaroxaban 10 mg tablet, 10

9465E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	37.59	38.30	Xarelto [BN]

NP

▪ RIVAROXABAN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Shared Care Model:

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

Authority required (STREAMLINED)

4402

Prevention of venous thromboembolism

Clinical criteria:

Patient must require up to 30 days supply to complete a course of treatment.

Treatment criteria:

Patient must be undergoing total hip replacement.

RIVAROXABAN Tablet 10 mg, 30

9467G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	91.93	38.30	Xarelto [BN]

NP

rivaroxaban 10 mg tablet, 15

9466F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	51.18	38.30	Xarelto [BN]

NP

▪ RIVAROXABAN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Shared Care Model:

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

Authority required (STREAMLINED)

4381

Prevention of venous thromboembolism

Clinical criteria:

Patient must require up to 10 days of therapy.

Treatment criteria:

Patient must be undergoing total knee replacement.

rivaroxaban 10 mg tablet, 10

9468H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	37.59	38.30	Xarelto [BN]

NP

▪ RIVAROXABAN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Shared Care Model:

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

Authority required (STREAMLINED)

4382

Prevention of venous thromboembolism

Clinical criteria:

Patient must require up to 15 days of therapy.

Treatment criteria:

Patient must be undergoing total knee replacement.

rivaroxaban 10 mg tablet, 15

9469J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	51.18	38.30	Xarelto [BN]

▪ RIVAROXABAN

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

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

4269

Prevention of stroke or systemic embolism

Clinical criteria:

Patient must have non-valvular atrial fibrillation, AND

Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

rivaroxaban 15 mg tablet, 28

2691P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	86.50	38.30	Xarelto [BN]

▪ RIVAROXABAN

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

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4098

Deep vein thrombosis

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have confirmed acute symptomatic deep vein thrombosis, AND

Patient must not have symptomatic pulmonary embolism.

Authority required (STREAMLINED)

4260

Pulmonary embolism

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have confirmed acute symptomatic pulmonary embolism.

Note Special Pricing Arrangements apply.

rivaroxaban 15 mg tablet, 42

2160Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	124.54	38.30	Xarelto [BN]

▪ RIVAROXABAN

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

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4099

Deep vein thrombosis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have confirmed acute symptomatic deep vein thrombosis, AND

Patient must not have symptomatic pulmonary embolism.

Authority required (STREAMLINED)

4132

Prevention of recurrent venous thromboembolism

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a history of venous thromboembolism.

Authority required (STREAMLINED)

4268

Pulmonary embolism

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have confirmed acute symptomatic pulmonary embolism.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

4269

Prevention of stroke or systemic embolism

Clinical criteria:

Patient must have non-valvular atrial fibrillation, AND

Patient must have one or more risk factors for developing stroke or systemic embolism.

Risk factors for developing stroke or systemic ischaemic embolism are:

(i) Prior stroke (ischaemic or unknown type), transient ischaemic attack or non-central nervous system (CNS) systemic embolism;

(ii) age 75 years or older;

(iii) hypertension;

(iv) diabetes mellitus;

(v) heart failure and/or left ventricular ejection fraction 35% or less.

Note Special Pricing Arrangements apply.

rivaroxaban 20 mg tablet, 28

2268J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	86.50	38.30	Xarelto [BN]

Other antithrombotic agents

▪ FONDAPARINUX

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Shared Care Model:

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

Authority required (STREAMLINED)

5781

Prevention of venous thromboembolism

Treatment criteria:

Patient must be undergoing major hip surgery.

Authority required (STREAMLINED)

5808

Prevention of venous thromboembolism

Treatment criteria:

Patient must be undergoing total knee replacement.

FONDAPARINUX SODIUM Injection 2.5 mg in 0.5 mL single dose pre-filled syringe, 2

8775W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	3.5	..	..	*126.35	38.30	Arixtra [AS]

▪ ANTIHEMORRHAGICS

ANTIFIBRINOLYTICS

Amino acids

▪ TRANEXAMIC ACID

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

tranexamic acid 500 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2180R NP	1	2	..	49.14	38.30	Cyklokapron [PF]

▪ ANTIANEMIC PREPARATIONS

IRON PREPARATIONS

Iron bivalent, oral preparations

▪ FERROUS SULFATE

ferrous sulfate 30 mg/mL (equivalent to 6 mg/mL elemental iron) oral liquid, 250 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8815Y NP	‡1	2	..	21.10	22.27	Ferro-Liquid [AE]

Iron, parenteral preparations

▪ IRON

iron (as ferric carboxymaltose) 500 mg/10 mL injection, 1 x 10 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10104T NP	2	1	..	*306.81	38.30	ferinject [VL]

▪ IRON POLYMALTOSE

iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2593L NP	1	..	..	23.02	24.19	[a] Ferrosig [SI]	[a] Ferrum H [AS]

▪ IRON POLYMALTOSE

Authority required (STREAMLINED)
4302
Iron deficiency anaemia
Treatment criteria:
Patient must be undergoing chronic haemodialysis.

iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2805P NP	1	5	..	23.02	24.19	[a] Ferrosig [SI]	[a] Ferrum H [AS]

▪ IRON SUCROSE

iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10229J NP	1	..	..	31.16	32.33	Venofer [AS]

▪ IRON SUCROSE

Authority required (STREAMLINED)
4302
Iron deficiency anaemia
Treatment criteria:
Patient must be undergoing chronic haemodialysis.

iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8807M NP	1	5	..	31.16	32.33	Venofer [AS]

VITAMIN B12 AND FOLIC ACID

Vitamin B12 (cyanocobalamin and analogues)

▪ HYDROXOCOBALAMIN

Note One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin B12 deficiencies.

Note Pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as acetate) in 1 mL and pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as chloride) in 1 mL are equivalent for the purposes of substitution.

Restricted benefit
Pernicious anaemia
Population criteria:
Patient must identify as Aboriginal or Torres Strait Islander.

Restricted benefit
Proven vitamin B12 deficiencies other than pernicious anaemia
Population criteria:
Patient must identify as Aboriginal or Torres Strait Islander.

Restricted benefit
Anaemias associated with vitamin B12 deficiency
Clinical criteria:
Patient must have had a gastrectomy, AND
The treatment must be for prophylaxis.
Population criteria:
Patient must identify as Aboriginal or Torres Strait Islander.

hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2162T NP	1	..	..	14.69	15.86	[a] Vita-B12 [GH]

hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9048F NP	1	..	..	14.69	15.86	[a] Neo-B12 [HH]

Folic acid and derivatives

▪ FOLIC ACID

Restricted benefit
For treatment of a patient identifying as Aboriginal or Torres Strait Islander

folic acid 500 microgram tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2958Q NP	2	..	..	*14.49	15.66	[a] Foltabs 500 [PP]	[a] Megafol 0.5 [AF]

▪ FOLIC ACID

Note The 5 mg strength tablet should be used in malabsorption states only.

Restricted benefit
For treatment of a patient identifying as Aboriginal or Torres Strait Islander

folic acid 5 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1437P NP	2	1	..	*16.71	17.88	Megafol 5 [AF]

▪ BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

BLOOD AND RELATED PRODUCTS

Blood substitutes and plasma protein fractions

▪ GELATIN-SUCCINYLATED

gelatin-succinylated 20 g/500 mL injection, 500 mL bag

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8444K NP	3	..	..	*43.50	38.30	Gelofusine [BR]

▪ PENTASTARCH + SODIUM CHLORIDE

HYDROXYETHYL STARCH 130/0.4 I.V. infusion 30 g per 500 mL, 500 mL, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9487H NP	3	..	..	*43.50	38.30	Voluven 6% [PK]

▪ OTHER HEMATOLOGICAL AGENTS

OTHER HEMATOLOGICAL AGENTS

Drugs used in hereditary angioedema

▪ ICATIBANT

Note Icatibant should be provided in the framework of a comprehensive hereditary angioedema prophylaxis program and an emergency Action Plan including training in recognition of the symptoms of hereditary angioedema and the self-administration of icatibant. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au)

Authority required

Anticipated emergency treatment of an acute attack of hereditary angioedema

Treatment Phase: Initial

Clinical criteria:

Patient must have confirmed diagnosis of C1-esterase inhibitor deficiency, AND

Patient must have been assessed to be at significant risk of an acute attack of hereditary angioedema, AND

The condition must be assessed by a clinical immunologist; OR

The condition must be assessed by a respiratory physician; OR

The condition must be assessed by a specialist allergist; OR

The condition must be assessed by a general physician experienced in the management of patients with hereditary angioedema.

The name of the specialist consulted must be provided at the time of application for initial supply.

The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.

Authority required

Anticipated emergency treatment of an acute attack of hereditary angioedema

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug.

ICATIBANT Injection 30 mg (as acetate) in 3 mL single use pre-filled syringe, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1976B	1	1	..	2571.87	38.30	Firazyr [ZI]

▪ CARDIOVASCULAR SYSTEM

▪ CARDIAC THERAPY

CARDIAC GLYCOSIDES

Digitalis glycosides

▪ DIGOXIN

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

digoxin 250 microgram tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1322N NP	1	1	..	14.15	15.32	[a] Sigmaxin [FM]
			[B]2.56	16.71	15.32	[a] Lanoxin [QA]

digoxin 50 microgram/mL oral liquid, 60 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3164M NP	2	3	..	*40.63	38.30	Lanoxin [QA]

digoxin 62.5 microgram tablet, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2605D NP	1	1	..	13.90	15.07	[a] Sigmaxin-PG [FM]
			[B]2.56	16.46	15.07	[a] Lanoxin-PG [QA]

ANTIARRHYTHMICS, CLASS I AND III

Antiarrhythmics, class Ia

▪ DISOPYRAMIDE

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

disopyramide 100 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2923W NP	1	5	..	29.18	30.35	Rythmodan [SW]

disopyramide 150 mg capsule, 100

2924X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	44.24	38.30	Rythmodan [SW]

Antiarrhythmics, class Ib

▪ LIGNOCAINE

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

lignocaine hydrochloride anhydrous 500 mg/5 mL injection, 10 x 5 mL ampoules

2876J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	29.56	30.73	Xylocard 500 [AP]

Antiarrhythmics, class Ic

▪ FLECAINIDE

Caution Flecainide acetate should be avoided in patients with poor cardiac function.

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

Restricted benefit
Serious supra-ventricular cardiac arrhythmias

Restricted benefit
Serious ventricular cardiac arrhythmias
Clinical criteria:
The treatment must be initiated in a hospital.

flecainide acetate 100 mg tablet, 60

1090J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	44.19	38.30	[a] Flecatab [AF]	[a] Tambocor [IA]

flecainide acetate 50 mg tablet, 60

1088G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	37.65	38.30	Tambocor [IA]

Antiarrhythmics, class III

▪ AMIODARONE

Note This drug has been reported to cause frequent and potentially serious toxicity.

Note Regular monitoring of hepatic and thyroid function is recommended.

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

Restricted benefit
Severe cardiac arrhythmias

amiodarone hydrochloride 100 mg tablet, 30

2344J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.77	15.94	[a] Aratac 100 [AF]	[a] Cordarone X 100 [SW]

amiodarone hydrochloride 200 mg tablet, 30

2343H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.16	19.33	[a] Amiodarone Sandoz [SZ] [a] Chem mart Amiodarone [CH] [a] GenRx Amiodarone [GX] [a] Terry White Chemists Amiodarone [TW]	[a] Aratac 200 [AF] [a] Cordarone X 200 [SW] [a] Rithmik 200 [RW]

▪ SOTALOL

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

Restricted benefit
Severe cardiac arrhythmias

sotalol hydrochloride 160 mg tablet, 60

2043M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.29	19.46	[a] APO-Sotalol [TX]	[a] Cardol [AF]
						[a] Solavert [RF]	[a] Sotalol Sandoz [SZ]
			[B]2.89	21.18	19.46	[a] Sotacor [RW]	

sotalol hydrochloride 80 mg tablet, 60

8398B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.09	15.26	[a] APO-Sotalol [TX]	[a] GenRx Sotalol [GX]
						[a] Solavert [RF]	[a] Sotalol Sandoz [SZ]
			[B]2.88	16.97	15.26	[a] Sotacor [RW]	

CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES

Adrenergic and dopaminergic agents

▪ ADRENALINE

adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules

1016L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	1	..	21.91	23.08	Link Medical Products Pty Ltd [LM]

adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules

5004J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	21.91	23.08	Link Medical Products Pty Ltd [LM]

▪ ADRENALINE

Caution EpiPen and Anapen products have different administration techniques and should not be prescribed to the same patient without training in their use.

Note The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au.)

Note Authority approvals will be limited to a maximum quantity of 2 auto-injectors (Anapen or EpiPen) at any one time.

Note No applications for repeats will be authorised.

Authority required

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; OR

Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; OR

Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; OR

Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.

The name of the specialist consulted must be provided at the time of application for initial supply.

Authority required

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

Patient must have been discharged from hospital or an emergency department after treatment with adrenaline for acute allergic reaction with anaphylaxis.

Authority required

Acute allergic reaction with anaphylaxis

Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug.

adrenaline 150 microgram/0.3 mL injection, 0.3 mL syringe

3408J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	96.43	38.30	Anapen Junior [LM]

adrenaline 150 microgram/0.3 mL injection, 0.3 mL syringe

8697R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	96.43	38.30	EpiPen Jr. [AL]

adrenaline 300 microgram/0.3 mL injection, 0.3 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3409K NP	1	..	..	96.43	38.30	Anapen [LM]

adrenaline 300 microgram/0.3 mL injection, 0.3 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8698T NP	1	..	..	96.43	38.30	EpiPen [AL]

VASODILATORS USED IN CARDIAC DISEASES

Organic nitrates

▪ GLYCERYL TRINITRATE

glyceryl trinitrate 10 mg/24 hours patch, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1516T NP	1	5	..	31.69	32.86	Transiderm-Nitro 50 [NV]

glyceryl trinitrate 10 mg/24 hours patch, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8011P NP	1	5	..	31.69	32.86	Nitro-Dur 10 [MK]

glyceryl trinitrate 10 mg/24 hours patch, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8028M NP	1	5	..	31.69	32.86	Minitran 10 [IA]

glyceryl trinitrate 15 mg/24 hours patch, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8026K NP	1	5	..	31.69	32.86	Nitro-Dur 15 [MK]

glyceryl trinitrate 15 mg/24 hours patch, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8119H NP	1	5	..	31.69	32.86	Minitran 15 [IA]

glyceryl trinitrate 5 mg/24 hours patch, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1515R NP	1	5	..	26.64	27.81	Transiderm-Nitro 25 [NV]

glyceryl trinitrate 5 mg/24 hours patch, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8010N NP	1	5	..	26.64	27.81	Nitro-Dur 5 [MK]

glyceryl trinitrate 5 mg/24 hours patch, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8027L NP	1	5	..	26.64	27.81	Minitran 5 [IA]

glyceryl trinitrate 600 microgram tablet: sublingual, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1459T NP	‡1	5	..	17.73	18.90	[a] Lycinate [RF]
			[B]2.56	20.29	18.90	[a] Anginine Stabilised [RW]

glyceryl trinitrate 600 microgram tablet: sublingual, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5108W DP	‡1	..	..	17.73	18.90	[a] Lycinate [RF]
			[B]2.56	20.29	18.90	[a] Anginine Stabilised [RW]

▪ GLYCERYL TRINITRATE

Note The spray should not be inhaled.

glyceryl trinitrate 400 microgram/actuation spray, 200 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8171C NP	‡1	5	..	22.34	23.51	Nitrolingual Pumpspray [SW]

▪ ISOSORBIDE DINITRATE

isosorbide dinitrate 5 mg tablet: sublingual, 100

2588F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	2	..	*17.51	18.68	Isordil Sublingual [RW]

▪ ISOSORBIDE MONONITRATE

isosorbide mononitrate 120 mg tablet: modified release, 30

8273K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	18.60	19.77	[a] Monodur 120 mg [PM]
			[B]3.37	21.97	19.77	[a] Imdur 120 mg [AP]

isosorbide mononitrate 60 mg tablet: modified release, 30

1558B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.88	15.05	[a] Chem mart Isosorbide Mononitrate [CH]	[a] Duride [AF]
						[a] GenRx Isosorbide Mononitrate [GX]	[a] Imtrate 60 mg [ED]
						[a] Isomonit [SZ]	[a] Isosorbide AN [EA]
						[a] Terry White Chemists Isosorbide Mononitrate [TW]	
			[B]2.48	16.36	15.05	[a] Monodur 60 mg [PM]	
			[B]3.37	17.25	15.05	[a] Imdur Durule [AP]	

Other vasodilators used in cardiac diseases

▪ NICORANDIL

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

nicorandil 10 mg tablet, 60

8228C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	5	..	24.40	25.57	[a] Ikorel [SW]	[a] Ikotab [QA]

nicorandil 20 mg tablet, 60

8229D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	5	..	29.89	31.06	[a] Ikorel [SW]	[a] Ikotab [QA]

▪ PERHEXILINE

Note Regular monitoring of drug serum levels is recommended.

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

Authority required (STREAMLINED)
5592
Angina
Clinical criteria:
The condition must not be responding to other therapy.

perhexiline maleate 100 mg tablet, 100

1822X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	58.95	38.30	Pexsig [QA]

OTHER CARDIAC PREPARATIONS

Other cardiac preparations

▪ IVABRADINE

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

Authority required (STREAMLINED)
4979
Chronic heart failure
Clinical criteria:

Patient must be symptomatic with NYHA classes II or III, AND
Patient must be in sinus rhythm, AND
Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%, AND
Patient must have a resting heart rate at or above 77 bpm at the time ivabradine treatment is initiated, AND
Patient must receive concomitant optimal standard chronic heart failure treatment, which must include the maximum tolerated dose of a beta-blocker, unless contraindicated or not tolerated.
Resting heart rate should be measured by ECG or echocardiography, after 5 minutes rest.
The ECG or echocardiography, result must be documented in the patient's medical records when treatment is initiated.

ivabradine 5 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10012Y NP	1	5	..	55.58	38.30	Coralan [SE]

ivabradine 7.5 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2960T NP	1	5	..	55.58	38.30	Coralan [SE]

ANTIHYPERTENSIVES

ANTIADRENERGIC AGENTS, CENTRALLY ACTING

Methyldopa

METHYLDOPA

methyldopa 250 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1629R NP	1	5	..	19.22	20.39	[a] Hydopa [AF]
			[B]3.08	22.30	20.39	[a] Aldomet [AS]

Imidazoline receptor agonists

CLONIDINE

clonidine hydrochloride 100 microgram tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3145M NP	1	5	..	28.97	30.14	Catapres 100 [BY]

clonidine hydrochloride 150 microgram tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3141H NP	1	5	..	36.04	37.21	Catapres [BY]

MOXONIDINE

Restricted benefit
Hypertension
Clinical criteria:
Patient must be receiving concurrent antihypertensive therapy.

moxonidine 200 microgram tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9019Q NP	1	5	..	21.25	22.42	Physiotens [GO]

moxonidine 400 microgram tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9020R NP	1	5	..	28.89	30.06	Physiotens [GO]

ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING

Alpha-adrenoreceptor antagonists

PRAZOSIN

prazosin 1 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1479W NP	1	5	..	14.11	15.28	[a] APO-Prazosin [TX] [a] Minipress [PF]	[a] Chem mart Prazosin [CH] [a] Terry White Chemists Prazosin [TW]

prazosin 2 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1480X NP	1	5	..	16.30	17.47	[a] APO-Prazosin [TX]	[a] Chem mart Prazosin [CH]

						[a] Minipress [PF]	[a] Terry White Chemists Prazosin [TW]

prazosin 5 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1478T NP	1	5	..	20.98	22.15	[a] APO-Prazosin [TX] [a] Minipress [PF]	[a] Chem mart Prazosin [CH] [a] Terry White Chemists Prazosin [TW]

ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON

Hydrazinophthalazine derivatives

▪ HYDRALAZINE

hydralazine hydrochloride 25 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1640H NP	2	2	..	*19.41	20.58	Alphapress 25 [AF]

hydralazine hydrochloride 50 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1639G NP	2	2	..	*20.85	22.02	Alphapress 50 [AF]

Pyrimidine derivatives

▪ MINOXIDIL

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

Restricted benefit
Severe refractory hypertension
Clinical criteria:
The treatment must be initiated by a consultant physician.

minoxidil 10 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2313R NP	1	5	..	56.92	38.30	Loniten [PF]

▪ DIURETICS

LOW-CEILING DIURETICS, THIAZIDES

Thiazides, plain

▪ HYDROCHLOROTHIAZIDE

hydrochlorothiazide 25 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1484D NP	1	1	..	22.67	23.84	Dithiazide [PL]

LOW-CEILING DIURETICS, EXCL. THIAZIDES

Sulfonamides, plain

▪ CHLORTHALIDONE

chlorthalidone 25 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1585K NP	2	1	..	*19.63	20.80	Hygroton 25 [ZC]

▪ INDAPAMIDE

indapamide hemihydrate 1.5 mg tablet: modified release, 90

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8532C NP	1	1	..	21.62	22.79	[a] APO-Indapamide SR [TX] [a] Natrilix SR [SE] [a] Tenaxil SR [RW]	[a] Chem mart Indapamide SR [CH] [a] Odaplix SR [AF] [a] Terry White Chemists Indapamide SR [TW]

indapamide hemihydrate 2.5 mg tablet, 90

2436F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	18.10	19.27	[a] Chem mart Indapamide [CH] [a] GenRx Indapamide [GX] [a] Indapamide-GA [ED] [a] Insig [RW]	[a] Dapa-Tabs [AF] [a] Indapamide AN [EA] [a] Indapamide Sandoz [SZ] [a] Terry White Chemists Indapamide [TW]
			[B]4.11	22.21	19.27	[a] Natrilix [SE]	

HIGH-CEILING DIURETICS

Sulfonamides, plain

▪ FRUSEMIDE

frusemide 10 mg/mL oral liquid, 30 mL

2411X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	3	..	26.44	27.61	Lasix [SW]

frusemide 20 mg/2 mL injection, 5 x 2 mL ampoules

2413B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	11.88	13.05	[a] Frusemide-Claris [AE] [a] Lasix [SW]	[a] Frusemide Sandoz [SZ]

frusemide 40 mg tablet, 100

2412Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	11.63	12.80	Urex [RW] [a] APO-Frusemide [TX] [a] Frusax [ER] [a] Frusemide Sandoz [SZ] [a] GenRx Frusemide [GX] [a] Uremide [AF]	[a] Chem mart Frusemide [CH] [a] Frusemide RBX [RA] [a] Frusid [EA] [a] Terry White Chemists Frusemide [TW]
			[B]1.85	13.48	12.80	[a] Lasix [SW]	

frusemide 500 mg tablet, 50

2415D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	3	..	16.73	17.90	Urex-Forte [RW]

▪ FRUSEMIDE

Note For item codes 2414C and 1810G, pharmaceutical benefits that have the form tablet 20 mg are equivalent for the purposes of substitution.

frusemide 20 mg tablet, 100

2414C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	11.75	12.92	[a] APO-Frusemide [TX] [a] Frusemide RBX [RA] [a] GenRx Frusemide [GX]	[a] Chem mart Frusemide [CH] [a] Frusid [EA] [a] Terry White Chemists Frusemide [TW]

frusemide 20 mg tablet, 50

1810G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	1	..	*11.77	12.94	[a] Urex-M [RW]
			[B]1.46	*13.23	12.94	[a] Lasix-M [SW]

Aryloxyacetic acid derivatives

▪ ETHACRYNIC ACID

Restricted benefit

Patients hypersensitive to other oral diuretics

ethacrynic acid 25 mg tablet, 100

8748K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	1	..	*175.27	38.30	Edecrin [FK]

POTASSIUM-SPARING AGENTS

Aldosterone antagonists

▪ EPLERENONE

Caution Serum electrolytes should be checked regularly

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

Authority required (STREAMLINED)

4937

Heart failure with a left ventricular ejection fraction of 40% or less

Clinical criteria:

The condition must occur within 3 to 14 days following an acute myocardial infarction, AND

The treatment must be commenced within 14 days of an acute myocardial infarction.

The date of the acute myocardial infarction and the date of initiation of treatment with this drug must be documented in the patient's medical records when PBS-subsidised treatment is initiated

eplerenone 25 mg tablet, 30

8879H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	87.57	38.30	[a] Inpler [AF]	[a] Inspra [PF]

eplerenone 50 mg tablet, 30

8880J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	87.57	38.30	[a] Inpler [AF]	[a] Inspra [PF]

▪ SPIRONOLACTONE

Caution Serum electrolytes should be checked regularly

Appropriate contraceptive measures should be taken by women of child-bearing age in whom spironolactone therapy has been initiated.

spironolactone 100 mg tablet, 100

2340E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	30.16	31.33	[a] Spiractin 100 [AF]
			[B]6.17	36.33	31.33	[a] Aldactone [PF]

spironolactone 25 mg tablet, 100

2339D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	15.44	16.61	[a] Spiractin 25 [AF]
			[B]5.59	21.03	16.61	[a] Aldactone [PF]

DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION

Low-ceiling diuretics and potassium-sparing agents

▪ AMILORIDE + HYDROCHLOROTHIAZIDE

Caution Serum electrolytes should be checked regularly.

amiloride hydrochloride 5 mg + hydrochlorothiazide 50 mg tablet, 50

1486F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	1	..	*16.59	17.76	Moduretic [AS]

▪ HYDROCHLOROTHIAZIDE + TRIAMTERENE

Caution Serum electrolytes should be checked regularly.

hydrochlorothiazide 25 mg + triamterene 50 mg tablet, 100

1280J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	1	..	16.05	17.22	Hydrene 25/50 [AF]

▪ PERIPHERAL VASODILATORS

PERIPHERAL VASODILATORS

Other peripheral vasodilators

▪ PHENOXYBENZAMINE

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

Restricted benefit

Phaeochromocytoma

Restricted benefit

Neurogenic urinary retention

phenoxybenzamine hydrochloride 10 mg capsule, 100

1862B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	1102.60	38.30	Dibenyline [GH]

phenoxybenzamine hydrochloride 10 mg capsule, 100

9286R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	1102.60	38.30	Dibenzyline [BZ]

phenoxybenzamine hydrochloride 10 mg capsule, 30

1166J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	3	5	..	*997.08	38.30	Amdipharm Mercury (Australia) Pty Limited [GH]

▪ BETA BLOCKING AGENTS

BETA BLOCKING AGENTS

Beta blocking agents, non-selective

▪ OXPRENOLOL

oxprenolol hydrochloride 40 mg tablet, 100

2961W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	45.87	38.30	Corbeton 40 [AF]

▪ PINDOLOL

pindolol 5 mg tablet, 100

3062E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	31.30	32.47	Barbloc 5 [AF]

▪ PROPRANOLOL

propranolol hydrochloride 10 mg tablet, 100

2565B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.17	14.34	[a] APO-Propranolol [TX]	[a] Deralin 10 [AF]
			[B]3.75	16.92	14.34	[a] Inderal [AP]	

propranolol hydrochloride 160 mg tablet, 50

2899N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	14.83	16.00	Deralin 160 [AF]

propranolol hydrochloride 40 mg tablet, 100

2566C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.44	14.61	[a] APO-Propranolol [TX]	[a] Deralin 40 [AF]
			[B]3.75	17.19	14.61	[a] Inderal [AP]	

Beta blocking agents, selective

▪ ATENOLOL

atenolol 50 mg tablet, 30

1081X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	11.56	12.73	[a] APO-Atenolol [TX] [a] Atenolol-GA [ED] [a] Atenolol RBX [RA] [a] Chem mart Atenolol [CH] [a] Tenolten 50 [DO] [a] Terry White Chemists Atenolol [TW]	[a] Atenolol AN [EA] [a] Atenolol GH [GQ] [a] Atenolol Sandoz [SZ] [a] Noten [AF] [a] Tensig [RW]
			[B]2.44	14.00	12.73	[a] Tenormin [AP]	

▪ ATENOLOL

Restricted benefit

For a patient who is unable to take a solid dose form of atenolol.

atenolol 50 mg/10 mL oral liquid, 300 mL

2243C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	28.70	29.87	Atenolol-AFT [AE]

▪ BISOPROLOL

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

Restricted benefit

Moderate to severe heart failure

Clinical criteria:

Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

bisoprolol fumarate 10 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8606Y NP	1	5	..	28.30	29.47	[a] APO-Bisoprolol [TX] [a] Bicard 10 [RW] [a] Bisoprolol AN [EA] [a] Bisoprolol Sandoz [SZ] [a] Chem mart Bisoprolol [CH]	[a] Beprol 10 [DO] [a] Biso 10 [ED] [a] Bisoprolol generichealth [GQ] [a] Bispro 10 [AF] [a] Terry White Chemists Bisoprolol [TW]
			[B]3.57	31.87	29.47	[a] Bicor [AL]	

bisoprolol fumarate 2.5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8604W NP	1	5	..	21.86	23.03	[a] APO-Bisoprolol [TX] [a] Bicard 2.5 [RW] [a] Bisoprolol AN [EA] [a] Bisoprolol Sandoz [SZ] [a] Chem mart Bisoprolol [CH]	[a] Beprol 2.5 [DO] [a] Biso 2.5 [ED] [a] Bisoprolol generichealth [GQ] [a] Bispro 2.5 [AF] [a] Terry White Chemists Bisoprolol [TW]
			[B]3.57	25.43	23.03	[a] Bicor [AL]	

bisoprolol fumarate 5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8605X NP	1	5	..	24.72	25.89	[a] APO-Bisoprolol [TX] [a] Bicard 5 [RW] [a] Bisoprolol AN [EA] [a] Bisoprolol Sandoz [SZ] [a] Chem mart Bisoprolol [CH]	[a] Beprol 5 [DO] [a] Biso 5 [ED] [a] Bisoprolol generichealth [GQ] [a] Bispro 5 [AF] [a] Terry White Chemists Bisoprolol [TW]
			[B]3.57	28.29	25.89	[a] Bicor [AL]	

▪ METOPROLOL SUCCINATE

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

Restricted benefit

Moderate to severe heart failure

Clinical criteria:

Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8735R NP	1	5	..	78.22	38.30	[a] Metrol-XL 190 [RW] [a] Toprol-XL 190 [AP]	[a] Minax XL [AF]

METOPROLOL SUCCINATE Tablet 23.75 mg (controlled release), 15

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8732N NP	1	..	..	19.61	20.78	[a] Metrol-XL 23.75 [RW] [a] Toprol-XL 23.75 [AP]	[a] Minax XL [AF]

METOPROLOL SUCCINATE Tablet 47.5 mg (controlled release), 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8733P NP	1	5	..	53.83	38.30	[a] Metrol-XL 47.5 [RW] [a] Toprol-XL 47.5 [AP]	[a] Minax XL [AF]

METOPROLOL SUCCINATE Tablet 95 mg (controlled release), 30

8734Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	64.66	38.30	[a] Metrol-XL 95 [RW] [a] Toprol-XL 95 [AP]	[a] Minax XL [AF]

▪ METOPROLOL TARTRATE

METOPROLOL TARTRATE Tablet 100 mg, 60

1325R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.13	14.30	[a] Metoprolol Actavis [ED] [a] Metoprolol RBX [RA] [b] APO-Metoprolol [TX] [b] GenRx Metoprolol [GX] [b] Metrol 100 [RW] [b] Terry White Chemists Metoprolol [TW]	[a] Metoprolol AN [EA] [a] Mistrom [ER] [b] Chem mart Metoprolol [CH] [b] Metoprolol Sandoz [SZ] [b] Minax 100 [AF]
			[B]2.00	15.13	14.30	[a] Lopresor 100 [NV]	
			[B]3.76	16.89	14.30	[b] Betaloc [AP]	

METOPROLOL TARTRATE Tablet 50 mg, 100

1324Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.55	13.72	[a] Metoprolol Actavis [ED] [a] Metoprolol RBX [RA] [b] APO-Metoprolol [TX] [b] GenRx Metoprolol [GX] [b] Metrol 50 [RW] [b] Terry White Chemists Metoprolol [TW]	[a] Metoprolol AN [EA] [a] Mistrom [ER] [b] Chem mart Metoprolol [CH] [b] Metoprolol Sandoz [SZ] [b] Minax 50 [AF]
			[B]2.01	14.56	13.72	[a] Lopresor 50 [NV]	
			[B]3.76	16.31	13.72	[b] Betaloc [AP]	

▪ NEBIVOLOL

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

Restricted benefit
Moderate to severe heart failure
Clinical criteria:
Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

nebivolol 1.25 mg tablet, 28

9316H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*48.15	38.30	Nebilet [FK]

nebivolol 10 mg tablet, 28

9312D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	63.62	38.30	Nebilet [FK]

nebivolol 5 mg tablet, 28

9311C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	57.50	38.30	Nebilet [FK]

Alpha and beta blocking agents

▪ CARVEDILOL

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

Restricted benefit
Moderate to severe heart failure
Clinical criteria:
Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

Restricted benefit
Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002

carvedilol 12.5 mg tablet, 60

8257N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	24.53	25.70	[a] APO-Carvedilol [TX]	[a] Carvedilol AN [EA]
						[a] Carvedilol generichealth [GQ]	[a] Carvedilol Sandoz [SZ]
						[a] Chem mart Carvedilol 12.5 mg [CH]	[a] Dicarz [AF]
						[a] Dilatrend 12.5 [RO]	[a] GN-Carvedilol [ED]
						[a] Terry White Chemists Carvedilol 12.5 mg [TW]	[a] Vedilol 12.5 [RW]
						[a] Volirop 12.5 [DO]	

carvedilol 25 mg tablet, 60

8258P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	28.05	29.22	[a] APO-Carvedilol [TX]	[a] Carvedilol AN [EA]
						[a] Carvedilol generichealth [GQ]	[a] Carvedilol Sandoz [SZ]
						[a] Chem mart Carvedilol 25 mg [CH]	[a] Dicarz [AF]
						[a] Dilatrend 25 [RO]	[a] GN-Carvedilol [ED]
						[a] Terry White Chemists Carvedilol 25 mg [TW]	[a] Vedilol 25 [RW]
						[a] Volirop 25 [DO]	

carvedilol 3.125 mg tablet, 30

8255L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	12.81	13.98	[a] APO-Carvedilol [TX]	[a] Carvedilol AN [EA]
						[a] Chem mart Carvedilol 3.125 mg [CH]	[a] Dilatrend 3.125 [RO]
						[a] GN-Carvedilol [ED]	[a] Terry White Chemists Carvedilol 3.125 mg [TW]
						[a] Vedilol 3.125 [RW]	[a] Volirop 3.125 [DO]

carvedilol 6.25 mg tablet, 60

8256M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.70	22.87	[a] APO-Carvedilol [TX]	[a] Carvedilol AN [EA]
						[a] Carvedilol generichealth [GQ]	[a] Carvedilol Sandoz [SZ]
						[a] Chem mart Carvedilol 6.25 mg [CH]	[a] Dicarz [AF]
						[a] Dilatrend 6.25 [RO]	[a] GN-Carvedilol [ED]
						[a] Terry White Chemists Carvedilol 6.25 mg [TW]	[a] Vedilol 6.25 [RW]
						[a] Volirop 6.25 [DO]	

▪ LABETALOL

labetalol hydrochloride 100 mg tablet, 100

1566K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	18.80	19.97	[a] Presolol 100 [AF]
			[B]3.50	22.30	19.97	[a] Trandate [QA]

labetalol hydrochloride 200 mg tablet, 100

1567L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	23.67	24.84	[a] Presolol 200 [AF]
			[B]3.50	27.17	24.84	[a] Trandate [QA]

▪ CALCIUM CHANNEL BLOCKERS

SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS

Dihydropyridine derivatives

▪ AMLODIPINE

amlodipine 10 mg tablet, 30

2752W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.31	13.48	[a] Amlo 10 [RW]	[a] Amlodipine AN [EA]
						[a] Amlodipine generichealth [GQ]	[a] Amlodipine Sandoz [SZ]
						[a] APO-Amlodipine [TX]	[a] Auro-Amlodipine 10 [DO]
						[a] Blooms the Chemist Amlodipine [IB]	[a] Chem mart Amlodipine [CH]
						[a] Nordip [AF]	[a] Norvapine [ED]
						[a] Ozlodip [RA]	[a] Pharmacor Amlodipine [CR]

						[a] Terry White Chemists Amlodipine [TW]	
			[B]8.15	20.46	13.48	[a] Norvasc [PF]	

amlodipine 5 mg tablet, 30

2751T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	11.50	12.67	[a] Amlo 5 [RW]	[a] Amlodipine AN [EA]
						[a] Amlodipine generichealth [GQ]	[a] Amlodipine Sandoz [SZ]
						[a] APO-Amlodipine [TX]	[a] Auro-Amlodipine 5 [DO]
						[a] Blooms the Chemist Amlodipine [IB]	[a] Chem mart Amlodipine [CH]
						[a] Nordip [AF]	[a] Norvapine [ED]
						[a] Ozlodip [RA]	[a] Pharmacor Amlodipine [CR]
						[a] Terry White Chemists Amlodipine [TW]	
			[B]6.29	17.79	12.67	[a] Norvasc [PF]	

▪ FELODIPINE

felodipine 10 mg tablet: modified release, 30

2367N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.83	20.00	[a] Felodil XR 10 [RW]	[a] Felodur ER 10 mg [TX]
						[a] Fendex ER [AF]	
			[B]2.40	21.23	20.00	[a] Plendil ER [GX]	

felodipine 2.5 mg tablet: modified release, 30

2361G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.65	14.82	[a] Felodur ER 2.5 mg [TX]	[a] Fendex ER [AF]
			[B]2.39	16.04	14.82	[a] Plendil ER [GX]	

felodipine 5 mg tablet: modified release, 30

2366M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.06	16.23	[a] Felodil XR 5 [RW]	[a] Felodur ER 5 mg [TX]
						[a] Fendex ER [AF]	
			[B]2.40	17.46	16.23	[a] Plendil ER [GX]	

▪ LERCANIDIPINE

lercanidipine hydrochloride 10 mg tablet, 28

8534E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.08	14.25	[a] APO-Lercanidipine [TX]	[a] Blooms the Chemist Lercanidipine [IB]
						[a] Chem mart Lercanidipine [CH]	[a] Ledip [RA]
						[a] Lercadip [EA]	[a] Lercan [RW]
						[a] Lercanidipine GH [GQ]	[a] Lercanidipine Sandoz [SZ]
						[a] Terry White Chemists Lercanidipine [TW]	[a] Zircol [AF]
			[B]3.50	16.58	14.25	[a] Zanidip [GO]	

lercanidipine hydrochloride 20 mg tablet, 28

8679T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.85	16.02	[a] APO-Lercanidipine [TX]	[a] Blooms the Chemist Lercanidipine [IB]
						[a] Chem mart Lercanidipine [CH]	[a] Ledip [RA]
						[a] Lercadip [EA]	[a] Lercan [RW]
						[a] Lercanidipine GH [GQ]	[a] Lercanidipine Sandoz [SZ]
						[a] Terry White Chemists Lercanidipine [TW]	[a] Zircol [AF]
			[B]3.50	18.35	16.02	[a] Zanidip [GO]	

▪ NIFEDIPINE

nifedipine 10 mg tablet, 60

1694E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	16.01	17.18	[a] Adefin 10 [AF]
			[B]1.84	17.85	17.18	[a] Adalat 10 [BN]

nifedipine 20 mg tablet, 60

1695F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.30	18.47	[a] Adefin 20 [AF]	[a] GenRx Nifedipine [GX]
			[B]2.57	19.87	18.47	[a] Adalat 20 [BN]	

nifedipine 20 mg tablet: modified release, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8610E NP	1	5	..	17.57	18.74	Adalat Oros 20mg [BN]

nifedipine 30 mg tablet: modified release, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1906H NP	1	5	..	18.15	19.32	[a] Addos XR 30 [RW] [a] APO-Nifedipine XR [TX]	[a] Adefin XL 30 [AF]
			[B]2.82	20.97	19.32	[a] Adalat Oros 30 [BN]	

nifedipine 60 mg tablet: modified release, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1907J NP	1	5	..	20.13	21.30	[a] Addos XR 60 [RW] [a] APO-Nifedipine XR [TX]	[a] Adefin XL 60 [AF]
			[B]2.99	23.12	21.30	[a] Adalat Oros 60 [BN]	

SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS

Phenylalkylamine derivatives

▪ VERAPAMIL

Caution The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

verapamil hydrochloride 160 mg capsule: modified release, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2206D NP	1	5	..	15.40	16.57	Veracaps SR [RW]

verapamil hydrochloride 180 mg tablet: modified release, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2208F NP	1	5	..	16.45	17.62	[a] Cordilox 180 SR [GT]
			[B]3.50	19.95	17.62	[a] Isoptin 180 SR [GO]

verapamil hydrochloride 240 mg capsule: modified release, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2207E NP	1	5	..	18.53	19.70	Veracaps SR [RW]

verapamil hydrochloride 240 mg tablet: modified release, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1241H NP	1	5	..	18.46	19.63	[a] Cordilox SR [GT]
			[B]3.50	21.96	19.63	[a] Isoptin SR [GO]

verapamil hydrochloride 40 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1248Q NP	1	5	..	15.29	16.46	Anpec 40 [AF]

verapamil hydrochloride 80 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1250T NP	1	5	..	17.89	19.06	[a] Anpec 80 [AF]
			[B]3.50	21.39	19.06	[a] Isoptin [GO]

Benzothiazepine derivatives

▪ DILTIAZEM

Caution The myocardial depressant effects of this drug and of beta-blocking drugs are additive.

diltiazem hydrochloride 180 mg capsule: modified release, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1312C NP	1	5	..	17.94	19.11	[a] Cardizem CD [SW] [a] Vasocardol CD [AV]	[a] Diltiazem Sandoz CD [SZ]

diltiazem hydrochloride 240 mg capsule: modified release, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1313D NP	1	5	..	20.58	21.75	[a] Cardizem CD [SW] [a] Vasocardol CD [AV]	[a] Diltiazem Sandoz CD [SZ]

diltiazem hydrochloride 360 mg capsule: modified release, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8480H NP	1	5	..	23.74	24.91	[a] Cardizem CD [SW] [a] Vasocardol CD [AV]	[a] Diltiazem Sandoz CD [SZ]

diltiazem hydrochloride 60 mg tablet, 90

1335G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.20	18.37	[a] Cardizem [SW] [a] Diltiazem AN [EA] [a] Dilzem 60 mg [EF]	[a] Diltiazem Actavis [ED] [a] Diltiazem Sandoz [SZ] [a] Vasocardol [AV]

AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM

ACE INHIBITORS, PLAIN

ACE inhibitors, plain

CAPTOPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

captopril 12.5 mg tablet, 90

1147J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	15.04	16.21	[a] Captopril Sandoz [SZ]
			[B]3.95	18.99	16.21	[a] Zedace [AF]

captopril 25 mg tablet, 90

1148K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	17.11	18.28	[a] Captopril Sandoz [SZ]
			[B]3.88	20.99	18.28	[a] Capoten [RW]
			[B]3.95	21.06	18.28	[a] Zedace [AF]

captopril 50 mg tablet, 90

1149L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	23.61	24.78	[a] Captopril Sandoz [SZ]
			[B]3.01	26.62	24.78	[a] Capoten [RW]
			[B]3.95	27.56	24.78	[a] Zedace [AF]

CAPTOPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Patients unable to take a solid dose form of an ACE inhibitor.

captopril 5 mg/mL oral liquid, 95 mL

8760C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	106.24	38.30	Capoten [RW]

ENALAPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

enalapril maleate 10 mg tablet, 30

1368B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.44	15.61	[a] Acetec [AL] [a] Enalapril Actavis [ED] [a] Enalapril generichealth [GQ] [a] Malean [RW]	[a] APO-Enalapril [TX] [a] Enalapril AN [EA] [a] Enalapril Sandoz [SZ]
			[B]4.65	19.09	15.61	[a] Renitec [MK]	

enalapril maleate 20 mg tablet, 30

1369C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.54	16.71	[a] Acetec [AL] [a] Enalapril Actavis [ED] [a] Enalapril generichealth [GQ] [a] Malean [RW]	[a] APO-Enalapril [TX] [a] Enalapril AN [EA] [a] Enalapril Sandoz [SZ]
			[B]4.66	20.20	16.71	[a] Renitec 20 [MK]	

enalapril maleate 5 mg tablet, 30

1370D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.86	14.03	[a] Acetec [AL] [a] Enalapril Actavis [ED] [a] Enalapril generichealth [GQ] [a] Malean [RW]	[a] APO-Enalapril [TX] [a] Enalapril AN [EA] [a] Enalapril Sandoz [SZ]

FOSINOPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

fosinopril sodium 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1182F NP	1	5	..	15.74	16.91	[a] APO-Fosinopril [TX] [a] Monace 10 [AF]	[a] Fosipril 10 [RW] [a] Monopril [BQ]

fosinopril sodium 20 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1183G NP	1	5	..	18.38	19.55	[a] APO-Fosinopril [TX] [a] Monace 20 [AF]	[a] Fosipril 20 [RW] [a] Monopril [BQ]

▪ LISINOPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

lisinopril 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2457H NP	1	5	..	14.18	15.35	[a] APO-Lisinopril [TX] [a] Chem mart Lisinopril [CH] [a] Lisinopril AN [EA] [a] Lisinopril generichealth [GQ] [a] Terry White Chemists Lisinopril [TW]	[a] Auro-Lisinopril 10 [DO] [a] Fibsol 10 [RW] [a] Lisinopril-GA [ED] [a] Lisinopril Sandoz [SZ] [a] Zinopril 10 [AL]
			[B]2.49	16.67	15.35	[a] Prinivil 10 [MK]	
			[B]3.30	17.48	15.35	[a] Zestril [AP]	

lisinopril 20 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2458J NP	1	5	..	15.16	16.33	[a] APO-Lisinopril [TX] [a] Chem mart Lisinopril [CH] [a] Lisinopril AN [EA] [a] Lisinopril generichealth [GQ] [a] Terry White Chemists Lisinopril [TW]	[a] Auro-Lisinopril 20 [DO] [a] Fibsol 20 [RW] [a] Lisinopril-GA [ED] [a] Lisinopril Sandoz [SZ] [a] Zinopril 20 [AL]
			[B]2.49	17.65	16.33	[a] Prinivil 20 [MK]	
			[B]3.30	18.46	16.33	[a] Zestril [AP]	

lisinopril 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2456G NP	1	5	..	12.94	14.11	[a] APO-Lisinopril [TX] [a] Chem mart Lisinopril [CH] [a] Lisinopril AN [EA] [a] Lisinopril generichealth [GQ] [a] Terry White Chemists Lisinopril [TW]	[a] Auro-Lisinopril 5 [DO] [a] Fibsol 5 [RW] [a] Lisinopril-GA [ED] [a] Lisinopril Sandoz [SZ] [a] Zinopril 5 [AL]
			[B]3.30	16.24	14.11	[a] Zestril [AP]	

▪ PERINDOPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form perindopril erbumine 2 mg tablet and pharmaceutical benefits that have the form perindopril arginine 2.5 mg tablet are equivalent for the purposes of substitution.

perindopril arginine 2.5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9006B NP	1	5	[B]1.95	14.57	13.79	[a] Coversyl 2.5mg [SE]	[a] PREXUM 2.5 [RX]

perindopril erbumine 2 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3050M NP	1	5	..	12.62	13.79	[a] APO-Perindopril [TX] [a] Chem mart Perindopril [CH] [a] Indosyl Mono 2 [RW] [a] Perindo [AF] [a] Terry White Chemists Perindopril [TW]	[a] Blooms the Chemist Perindopril [IB] [a] Idaprex 2 [SZ] [a] Ozapace [RA] [a] Perindopril Actavis 2 [EA]

▪ PERINDOPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form perindopril erbumine 4 mg tablet and pharmaceutical benefits that have the form perindopril arginine 5 mg tablet are equivalent for the purposes of substitution.

perindopril arginine 5 mg tablet, 30

9007C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.53	15.70	[a] Coversyl 5mg [SE]	[a] PREXUM 5 [RX]

perindopril erbumine 4 mg tablet, 30

3051N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.53	15.70	[a] APO-Perindopril [TX]	[a] Blooms the Chemist Perindopril [IB]
						[a] Chem mart Perindopril [CH]	[a] Idaprex 4 [SZ]
						[a] Indosyl Mono 4 [RW]	[a] Ozapace [RA]
						[a] Perindo [AF]	[a] Perindopril Actavis 4 [ED]
						[a] Perindopril CH [EA]	[a] Perindopril generichealth [GQ]
						[a] Terry White Chemists Perindopril [TW]	

▪ PERINDOPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form perindopril erbumine 8 mg tablet and pharmaceutical benefits that have the form perindopril arginine 10 mg tablet are equivalent for the purposes of substitution.

perindopril arginine 10 mg tablet, 30

9008D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.71	17.88	[a] Coversyl 10mg [SE]	[a] PREXUM 10 [RX]

perindopril erbumine 8 mg tablet, 30

8704D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.71	17.88	[a] APO-Perindopril [TX]	[a] Blooms the Chemist Perindopril [IB]
						[a] Chem mart Perindopril [CH]	[a] Idaprex 8 [SZ]
						[a] Indosyl Mono 8 [RW]	[a] Ozapace [RA]
						[a] Perindo [AF]	[a] Perindopril Actavis 8 [ED]
						[a] Perindopril CH [EA]	[a] Perindopril generichealth [GQ]
						[a] Terry White Chemists Perindopril [TW]	

▪ QUINAPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

quinapril 10 mg tablet, 30

1969P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.89	16.06	[a] Acquin Aspen 10 [RW]	[a] APO-Quinapril [TX]
						[a] Aquinafil [EA]	[a] Qpril 10 [AF]
			[B]3.11	18.00	16.06	[a] Accupril [PF]	

quinapril 20 mg tablet, 30

1970Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.95	17.12	[a] Acquin Aspen 20 [RW]	[a] APO-Quinapril [TX]
						[a] Aquinafil [EA]	[a] Qpril 20 [AF]
						[a] Quinapril generichealth [GQ]	
			[B]3.10	19.05	17.12	[a] Accupril [PF]	

quinapril 5 mg tablet, 30

1968N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.55	14.72	[a] Acquin Aspen 5 [RW]	[a] APO-Quinapril [TX]
						[a] Aquinafil [EA]	[a] Qpril 5 [AF]
			[B]3.10	16.65	14.72	[a] Accupril [PF]	

▪ RAMIPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form ramipril 10 mg tablet and pharmaceutical benefits that have the form ramipril 10 mg capsule are equivalent for the purposes of substitution.

ramipril 10 mg capsule, 30

8470T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.66	15.83	[a] APO-Ramipril [TX]	[a] Chem mart Ramipril [CH]
						[a] GenRx Ramipril [GX]	[a] Pharmacor Ramipril 10 [CR]
						[a] Prilace 10 [RW]	[a] Ramace 10 mg [AV]
						[a] Ramipril CH [EA]	[a] Ramipril-GA [ED]

						[a] Ramipril generichealth [GQ]	[a] Ramipril Sandoz [SZ]
						[a] Ramipril Winthrop [WA]	[a] Terry White Chemists Ramipril [TW]
						[a] Tritace 10 mg [SW]	[a] Tryzan Caps 10 [AF]
						[a] Vascalace Caps 10 [DO]	

ramipril 10 mg tablet, 30

1316G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.66	15.83	[a] APO-Ramipril [TX]	[a] Chem mart Ramipril [CH]
						[a] Ramipril AN [EA]	[a] Ramipril RBX Tabs [RA]
						[a] Ramipril Sandoz [SZ]	[a] Ramipril Winthrop [WA]
						[a] Terry White Chemists Ramipril [TW]	[a] Tritace [SW]
						[a] Tryzan Tabs 10 [AF]	[a] Vascalace 10 [DO]

▪ RAMIPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form ramipril 1.25 mg tablet and pharmaceutical benefits that have the form ramipril 1.25 mg capsule are equivalent for the purposes of substitution.

ramipril 1.25 mg capsule, 30

9120B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	11.73	12.90	[a] APO-Ramipril [TX]	[a] Chem mart Ramipril [CH]
						[a] Terry White Chemists Ramipril [TW]	[a] Tryzan Caps 1.25 [AF]
						[a] Vascalace Caps 1.25 [DO]	

ramipril 1.25 mg tablet, 30

1944H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	11.73	12.90	[a] APO-Ramipril [TX]	[a] Chem mart Ramipril [CH]
						[a] Ramace 1.25 mg [AV]	[a] Ramipril AN [EA]
						[a] Ramipril Sandoz [SZ]	[a] Ramipril Winthrop [WA]
						[a] Terry White Chemists Ramipril [TW]	[a] Tritace 1.25 mg [SW]
						[a] Tryzan Tabs 1.25 [AF]	[a] Vascalace 1.25 [DO]

▪ RAMIPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form ramipril 2.5 mg tablet and pharmaceutical benefits that have the form ramipril 2.5 mg capsule are equivalent for the purposes of substitution.

ramipril 2.5 mg capsule, 30

9121C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.33	13.50	[a] APO-Ramipril [TX]	[a] Chem mart Ramipril [CH]
						[a] Ramipril-GA [EA]	[a] Ramipril generichealth [GQ]
						[a] Terry White Chemists Ramipril [TW]	[a] Tryzan Caps 2.5 [AF]
						[a] Vascalace Caps 2.5 [DO]	

ramipril 2.5 mg tablet, 30

1945J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.33	13.50	[a] APO-Ramipril [TX]	[a] Chem mart Ramipril [CH]
						[a] Prilace 2.5 [RW]	[a] Ramace 2.5 mg [AV]
						[a] Ramipril AN [EA]	[a] Ramipril RBX Tabs [RA]
						[a] Ramipril Sandoz [SZ]	[a] Ramipril Winthrop [WA]
						[a] Terry White Chemists Ramipril [TW]	[a] Tritace 2.5 mg [SW]
						[a] Tryzan Tabs 2.5 [AF]	[a] Vascalace 2.5 [DO]

▪ RAMIPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form ramipril 5 mg tablet and pharmaceutical benefits that have the form ramipril 5 mg capsule are equivalent for the purposes of substitution.

ramipril 5 mg capsule, 30

9122D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.82	13.99	[a] APO-Ramipril [TX]	[a] Chem mart Ramipril [CH]
						[a] Pharmacor Ramipril 5 [CR]	[a] Ramipril-GA [EA]
						[a] Ramipril generichealth [GQ]	[a] Terry White Chemists Ramipril [TW]

						[a] Tryzan Caps 5 [AF]	[a] Vascalace Caps 5 [DO]

ramipril 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1946K NP	1	5	..	12.82	13.99	[a] APO-Ramipril [TX]	[a] Chem mart Ramipril [CH]
						[a] Prilace 5 [RW]	[a] Ramace 5 mg [AV]
						[a] Ramipril AN [EA]	[a] Ramipril RBX Tabs [RA]
						[a] Ramipril Sandoz [SZ]	[a] Ramipril Winthrop [WA]
						[a] Terry White Chemists Ramipril [TW]	[a] Tritace 5 mg [SW]
						[a] Tryzan Tabs 5 [AF]	[a] Vascalace 5 [DO]

▪ TRANDOLAPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

trandolapril 1 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2792Y NP	1	5	..	14.39	15.56	[a] Dolapril 1 [RW]	[a] Tranalpha [AF]
			[B]3.50	17.89	15.56	[a] Gopten [GO]	

trandolapril 2 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2793B NP	1	5	..	15.20	16.37	[a] Dolapril 2 [RW]	[a] Tranalpha [AF]
			[B]3.50	18.70	16.37	[a] Gopten [GO]	

trandolapril 4 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8758Y NP	1	5	..	19.41	20.58	[a] Dolapril 4 [RW]	[a] Tranalpha [AF]
			[B]3.49	22.90	20.58	[a] Gopten [GO]	

trandolapril 500 microgram capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2791X NP	1	5	..	11.91	13.08	[a] Dolapril 0.5 [RW]	[a] Tranalpha [AF]
			[B]3.50	15.41	13.08	[a] Gopten [GO]	

ACE INHIBITORS, COMBINATIONS

ACE inhibitors and diuretics

▪ ENALAPRIL + HYDROCHLOROTHIAZIDE

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy, AND

The condition must be inadequately controlled with an ACE inhibitor; OR

The condition must be inadequately controlled with a thiazide diuretic.

enalapril maleate 20 mg + hydrochlorothiazide 6 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8477E NP	1	5	..	26.57	27.74	[a] Enalapril/HCT Sandoz [SZ]	[a] Renitec Plus 20/6 [MK]

▪ FOSINOPRIL + HYDROCHLOROTHIAZIDE

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy, AND

The condition must be inadequately controlled with an ACE inhibitor; OR

The condition must be inadequately controlled with a thiazide diuretic.

fosinopril sodium 10 mg + hydrochlorothiazide 12.5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8400D NP	1	5	..	23.38	24.55	Monoplus 10/12.5 [BQ]

fosinopril sodium 20 mg + hydrochlorothiazide 12.5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8401E NP	1	5	..	29.45	30.62	[a] APO-Fosinopril HCTZ 20/12.5 [TX]	[a] Fosetic 20/12.5 [ZP]

						[a] Fosinopril/HCT Actavis 20/12.5 [EA]	[a] Monoplus 20/12.5 [BQ]

▪ PERINDOPRIL + INDAPAMIDE

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

perindopril arginine 2.5 mg + indapamide hemihydrate 625 microgram tablet, 30

2190G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	13.26	14.43	Coversyl Plus LD 2.5mg/0.625mg [SE]

▪ PERINDOPRIL + INDAPAMIDE

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Note Pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate) and pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 5 mg perindopril arginine-1.25 mg indapamide hemihydrate) are equivalent for the purposes of substitution.

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy, AND

The condition must be inadequately controlled with an ACE inhibitor; OR

The condition must be inadequately controlled with a thiazide-like diuretic.

perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30

2845R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	15.81	16.98	[a] Coversyl Plus 5mg/1.25mg [SE]	[a] Prexum Combi 5/1.25 [RX]

perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30

8449Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	15.81	16.98	[a] Chem mart Perindopril/ Indapamide 4/1.25 [CH]	[a] GenRx Perindopril/ Indapamide 4/1.25 [GX]
					[a] Idaprex Combi 4/1.25 [SZ]	[a] Indosyl Combi 4/1.25 [RW]
					[a] Perindo Combi 4/1.25 [AF]	[a] Perindopril and Indapamide CH 4/1.25 [EA]
					[a] Perindopril Combi Actavis 4/1.25 [ED]	[a] Perindopril/ Indapamide GH 4/1.25 [GQ]
					[a] Terry White Chemists Perindopril/ Indapamide 4/1.25 [TW]	

▪ QUINAPRIL + HYDROCHLOROTHIAZIDE

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy, AND

The condition must be inadequately controlled with an ACE inhibitor; OR

The condition must be inadequately controlled with a thiazide diuretic.

quinapril 10 mg + hydrochlorothiazide 12.5 mg tablet, 30

8589C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	16.73	17.90	Accuretic 10/12.5mg [PF]

quinapril 20 mg + hydrochlorothiazide 12.5 mg tablet, 30

8590D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	17.79	18.96	Accuretic 20/12.5mg [PF]

ACE inhibitors and calcium channel blockers

▪ LERCANIDIPINE + ENALAPRIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy, AND

The condition must be inadequately controlled with an ACE inhibitor; OR

The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

lercanidipine hydrochloride 10 mg + enalapril maleate 10 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9144G NP	1	5	..	16.83	18.00	Zan-Extra 10/10 [GO]

lercanidipine hydrochloride 10 mg + enalapril maleate 20 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9145H NP	1	5	..	17.85	19.02	Zan-Extra 10/20 [GO]

▪ PERINDOPRIL + AMLODIPINE

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy, AND

The condition must be inadequately controlled with an ACE inhibitor; OR

The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

Restricted benefit

Stable coronary heart disease

Clinical criteria:

The treatment must not be for the initiation of therapy for coronary heart disease, AND

The condition must be stabilised by treatment with perindopril and amlodipine at the same doses.

perindopril arginine 10 mg + amlodipine 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9349C NP	1	5	..	18.60	19.77	[a] Reaptan 10/10 [RX]
			[B]1.94	20.54	19.77	[a] Coveram 10/10 [SE]

perindopril arginine 10 mg + amlodipine 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9348B NP	1	5	..	17.79	18.96	[a] Reaptan 10/5 [RX]
			[B]1.95	19.74	18.96	[a] Coveram 10/5 [SE]

perindopril arginine 5 mg + amlodipine 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9347Y NP	1	5	..	16.42	17.59	[a] Reaptan 5/10 [RX]
			[B]4.95	21.37	17.59	[a] Coveram 5/10 [SE]

perindopril arginine 5 mg + amlodipine 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9346X NP	1	5	..	15.60	16.77	[a] Reaptan 5/5 [RX]
			[B]1.95	17.55	16.77	[a] Coveram 5/5 [SE]

▪ RAMIPRIL + FELODIPINE

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy, AND

The condition must be inadequately controlled with an ACE inhibitor; OR

The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

ramipril 2.5 mg + felodipine 2.5 mg tablet: modified release, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2626F NP	1	5	..	15.56	16.73	Triasyn 2.5/2.5 [SW]

ramipril 5 mg + felodipine 5 mg tablet: modified release, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2629J NP	1	5	..	17.46	18.63	Triasyn 5.0/5.0 [SW]

▪ TRANDOLAPRIL + VERAPAMIL

Caution Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

The myocardial depressant effects of verapamil hydrochloride and of beta-blocking drugs are additive.

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy, AND

The condition must be inadequately controlled with an ACE inhibitor; OR
The condition must be inadequately controlled with verapamil.

trandolapril 2 mg + verapamil hydrochloride 180 mg tablet: modified release, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9387C NP	1	5	..	20.84	22.01	Tarka 2/180 [GO]

trandolapril 4 mg + verapamil hydrochloride 240 mg tablet: modified release, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2857J NP	1	5	..	26.91	28.08	Tarka 4/240 [GO]

ANGIOTENSIN II ANTAGONISTS, PLAIN

Angiotensin II antagonists, plain

▪ CANDESARTAN

candesartan cilexetil 16 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8297Q NP	1	5	..	17.49	18.66	[a] Adesan [AF] [a] Auro-Candesartan 16 [DO] [a] Candesartan Aspen 16 [RW] [a] Candesartan GH [GQ] [a] Candesartan Sandoz [SZ] [a] Pharmacor Candesartan 16 [CR]	[a] APO-Candesartan [TX] [a] Candesartan AN [EA] [a] Candesartan-GA [ED] [a] Candesartan RBX [RA] [a] Chem mart Candesartan [CH] [a] Terry White Chemists Candesartan [TW]
			[B]2.00	19.49	18.66	[a] Atacand [AP]	

candesartan cilexetil 32 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8889W NP	1	5	..	18.97	20.14	[a] Adesan [AF] [a] Auro-Candesartan 32 [DO] [a] Candesartan Aspen 32 [RW] [a] Candesartan GH [GQ] [a] Candesartan Sandoz [SZ] [a] Pharmacor Candesartan 32 [CR]	[a] APO-Candesartan [TX] [a] Candesartan AN [EA] [a] Candesartan-GA [ED] [a] Candesartan RBX [RA] [a] Chem mart Candesartan [CH] [a] Terry White Chemists Candesartan [TW]
			[B]2.00	20.97	20.14	[a] Atacand [AP]	

candesartan cilexetil 4 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8295N NP	1	5	..	11.22	12.39	[a] Adesan [AF] [a] Auro-Candesartan 4 [DO] [a] Candesartan Aspen 4 [RW] [a] Candesartan GH [GQ] [a] Candesartan Sandoz [SZ] [a] Pharmacor Candesartan 4 [CR]	[a] APO-Candesartan [TX] [a] Candesartan AN [EA] [a] Candesartan-GA [ED] [a] Candesartan RBX [RA] [a] Chem mart Candesartan [CH] [a] Terry White Chemists Candesartan [TW]
			[B]2.00	13.22	12.39	[a] Atacand [AP]	

candesartan cilexetil 8 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8296P NP	1	5	..	12.79	13.96	[a] Adesan [AF] [a] Auro-Candesartan 8 [DO] [a] Candesartan Aspen 8 [RW] [a] Candesartan GH [GQ] [a] Candesartan Sandoz [SZ] [a] Pharmacor Candesartan 8 [CR]	[a] APO-Candesartan [TX] [a] Candesartan AN [EA] [a] Candesartan-GA [ED] [a] Candesartan RBX [RA] [a] Chem mart Candesartan [CH] [a] Terry White Chemists Candesartan [TW]
			[B]2.00	14.79	13.96	[a] Atacand [AP]	

▪ EPROSARTAN

eprosartan 400 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8397Y NP	2	5	[T]7.00	*29.79	23.96	Teveten [GO]

eprosartan 600 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8447N NP	1	5	[T]3.50	29.41	27.08	Teveten [GO]

▪ EPROSARTAN

Authority required
Adverse effects occurring with all of the base-priced drugs
Authority required
Drug interactions occurring with all of the base-priced drugs
Authority required
Drug interactions expected to occur with all of the base-priced drugs
Authority required
Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance

eprosartan 400 mg tablet, 28

8951D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*29.79	30.96	Teveten [GO]

eprosartan 600 mg tablet, 28

5491B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	29.41	30.58	Teveten [GO]

▪ IRBESARTAN

irbesartan 150 mg tablet, 30

8247C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	13.43	14.60	[a] Abisart [AF] [a] Chem mart Irbesartan [CH] [a] Irbesartan AN [EA] [a] Irbesartan GH [GQ] [a] Irbesartan Sandoz [SZ] [a] Irprestan 150 [ZP]	[a] APO-Irbesartan [TX] [a] Irbesartan Actavis 150 [ED] [a] Irbesartan-GA [EF] [a] Irbesartan RBX [RA] [a] Irbesartan Winthrop [WA] [a] Terry White Chemists Irbesartan [TW]
		[B]1.90	15.33	14.60	[a] Avapro [AV]	[a] Karvea [SW]

irbesartan 300 mg tablet, 30

8248D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.42	17.59	[a] Abisart [AF] [a] Chem mart Irbesartan [CH] [a] Irbesartan AN [EA] [a] Irbesartan GH [GQ] [a] Irbesartan Sandoz [SZ] [a] Irprestan 300 [ZP]	[a] APO-Irbesartan [TX] [a] Irbesartan Actavis 300 [ED] [a] Irbesartan-GA [EF] [a] Irbesartan RBX [RA] [a] Irbesartan Winthrop [WA] [a] Terry White Chemists Irbesartan [TW]
		[B]1.90	18.32	17.59	[a] Avapro [AV]	[a] Karvea [SW]

irbesartan 75 mg tablet, 30

8246B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	12.53	13.70	[a] Abisart [AF] [a] Chem mart Irbesartan [CH] [a] Irbesartan AN [EA] [a] Irbesartan GH [GQ] [a] Irbesartan Sandoz [SZ] [a] Irprestan 75 [ZP]	[a] APO-Irbesartan [TX] [a] Irbesartan Actavis 75 [ED] [a] Irbesartan-GA [EF] [a] Irbesartan RBX [RA] [a] Irbesartan Winthrop [WA] [a] Terry White Chemists Irbesartan [TW]
		[B]1.90	14.43	13.70	[a] Avapro [AV]	[a] Karvea [SW]

▪ LOSARTAN

losartan potassium 25 mg tablet, 30

5452Y NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	15.89	17.06	Cozavan [AF]

losartan potassium 50 mg tablet, 30

8203R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*26.07	27.24	Cozavan [AF]

▪ OLMESARTAN MEDOXOMIL

olmesartan medoxomil 20 mg tablet, 30

2147B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	[T]3.50	21.91	19.58	Olmetec [MK]

olmesartan medoxomil 40 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2148C NP	1	5	[T]3.50	30.87	28.54	Olmetec [MK]

▪ OLMESARTAN MEDOXOMIL

Authority required
Adverse effects occurring with all of the base-priced drugs
Authority required
Drug interactions occurring with all of the base-priced drugs
Authority required
Drug interactions expected to occur with all of the base-priced drugs
Authority required
Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance

olmesartan medoxomil 20 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5492C NP	1	5	..	21.91	23.08	Olmetec [MK]

olmesartan medoxomil 40 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5493D NP	1	5	..	30.87	32.04	Olmetec [MK]

▪ TELMISARTAN

telmisartan 40 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8355R NP	1	5	..	14.01	15.18	[a] APO-Telmisartan [TX]	[a] Chem mart Telmisartan [CH]
						[a] Mizart [AF]	[a] Pharmacor Telmisartan 40 [CR]
						[a] Telmigen [ED]	[a] Telmisartan AN [EA]
						[a] Telmisartan-DRLA [RZ]	[a] Telmisartan GH [GQ]
						[a] Telmisartan RBX [RA]	[a] Telmisartan Sandoz [SZ]
						[a] Teltartan [RW]	[a] Terry White Chemists Telmisartan [TW]
			[B]1.61	15.62	15.18	[a] Micardis [BY]	

telmisartan 80 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8356T NP	1	5	..	20.82	21.99	[a] APO-Telmisartan [TX]	[a] Chem mart Telmisartan [CH]
						[a] Mizart [AF]	[a] Pharmacor Telmisartan 80 [CR]
						[a] Telmigen [ED]	[a] Telmisartan AN [EA]
						[a] Telmisartan-DRLA [RZ]	[a] Telmisartan GH [GQ]
						[a] Telmisartan RBX [RA]	[a] Telmisartan Sandoz [SZ]
						[a] Teltartan [RW]	[a] Terry White Chemists Telmisartan [TW]
			[B]1.61	22.43	21.99	[a] Micardis [BY]	

▪ VALSARTAN

valsartan 160 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9370E NP	1	5	..	21.85	23.02	[a] APO-Valsartan [TX]	[a] Dilart [AF]
						[a] Diovan [NV]	

valsartan 40 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9368C NP	1	..	..	16.53	17.70	[a] APO-Valsartan [TX]	[a] Dilart [AF]
						[a] Diovan [NV]	

valsartan 80 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9369D NP	1	5	..	19.32	20.49	[a] APO-Valsartan [TX]	[a] Dilart [AF]
						[a] Diovan [NV]	

▪ VALSARTAN

Note No applications for increased maximum quantities and/or repeats will be authorised for the 320 mg tablet.

valsartan 320 mg tablet, 28

9371F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	25.07	26.24	[a] APO-Valsartan [TX] [a] Diovan [NV]	[a] Dilart [AF]

ANGIOTENSIN II ANTAGONISTS, COMBINATIONS

Angiotensin II antagonists and diuretics

▪ CANDESARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy, AND

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a thiazide diuretic.

candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30

8504N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.12	20.29	[a] Adesan HCT 16/12.5 [AF] [a] Asartan HCT 16/12.5 [DO] [a] Candesartan HCT GH 16/12.5 [GQ] [a] Candesartan HCTZ AN 16/12.5 [EA] [a] Candesartan HCTZ RBX 16/12.5 [RA] [a] Pharmacor Candesartan HCT 16/12.5 [CR]	[a] APO-Candesartan HCTZ 16/12.5 [TX] [a] Candesartan Combi Aspen 16/12.5 [RW] [a] Candesartan/HCT Sandoz [SZ] [a] Candesartan HCTZ-GA 16/12.5 [ED] [a] Chem mart Candesartan HCTZ 16/12.5 [CH] [a] Terry White Chemists Candesartan HCTZ 16/12.5 [TW]
			[B]2.00	21.12	20.29	[a] Atacand Plus 16/12.5 [AP]	

candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30

9314F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.59	21.76	[a] Adesan HCT 32/12.5 [AF] [a] Asartan HCT 32/12.5 [DO] [a] Candesartan HCT GH 32/12.5 [GQ] [a] Candesartan HCTZ AN 32/12.5 [EA] [a] Candesartan HCTZ RBX 32/12.5 [RA] [a] Pharmacor Candesartan HCT 32/12.5 [CR]	[a] APO-Candesartan HCTZ 32/12.5 [TX] [a] Candesartan Combi Aspen 32/12.5 [RW] [a] Candesartan/HCT Sandoz [SZ] [a] Candesartan HCTZ-GA 32/12.5 [ED] [a] Chem mart Candesartan HCTZ 32/12.5 [CH] [a] Terry White Chemists Candesartan HCTZ 32/12.5 [TW]
			[B]2.00	22.59	21.76	[a] Atacand Plus 32/12.5 [AP]	

candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30

9315G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.21	23.38	[a] Adesan HCT 32/25 [AF] [a] Asartan HCT 32/25 [DO] [a] Candesartan HCT GH 32/25 [GQ] [a] Candesartan HCTZ AN 32/25 [EA] [a] Candesartan HCTZ RBX 32/25 [RA] [a] Pharmacor Candesartan HCT 32/25 [CR]	[a] APO-Candesartan HCTZ 32/25 [TX] [a] Candesartan Combi Aspen 32/25 [RW] [a] Candesartan/HCT Sandoz [SZ] [a] Candesartan HCTZ-GA 32/25 [ED] [a] Chem mart Candesartan HCTZ 32/25 [CH] [a] Terry White Chemists Candesartan HCTZ 32/25 [TW]
			[B]2.00	24.21	23.38	[a] Atacand Plus 32/25 [AP]	

▪ EPROSARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy, AND

The condition must be inadequately controlled with an angiotensin II antagonist; OR
The condition must be inadequately controlled with a thiazide diuretic.

eprosartan 600 mg + hydrochlorothiazide 12.5 mg tablet, 28

8624X NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	27.63	28.80	Teveten Plus 600/12.5 [GO]

▪ IRBESARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension
Clinical criteria:
The treatment must not be for the initiation of anti-hypertensive therapy, AND
The condition must be inadequately controlled with an angiotensin II antagonist; OR
The condition must be inadequately controlled with a thiazide diuretic.

irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30

8404H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	14.70	15.87	[a] Abisart HCT 150/12.5 [AF]	[a] APO-Irbesartan HCTZ [TX]
					[a] Chem mart Irbesartan HCTZ [CH]	[a] Irbesartan HCT Actavis 150/12.5 [ED]
					[a] Irbesartan HCT GH 150/12.5 [GQ]	[a] Irbesartan/HCT Sandoz [SZ]
					[a] Irbesartan HCT Winthrop 150/12.5 [WA]	[a] Irbesartan HCTZ AN 150/12.5 [EA]
					[a] Irbesartan HCTZ-GA 150/12.5 [EF]	[a] Irbesartan/HCTZ RBX 150/12.5 [RA]
					[a] KSART HCT 150/12.5 [RW]	[a] Terry White Chemists Irbesartan HCTZ [TW]
		[B]1.90	16.60	15.87	[a] Avapro HCT 150/12.5 [AV]	[a] Karvezide 150/12.5 [SW]

irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30

8405J NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	18.04	19.21	[a] Abisart HCT 300/12.5 [AF]	[a] APO-Irbesartan HCTZ [TX]
					[a] Chem mart Irbesartan HCTZ [CH]	[a] Irbesartan HCT Actavis 300/12.5 [ED]
					[a] Irbesartan HCT GH 300/12.5 [GQ]	[a] Irbesartan/HCT Sandoz [SZ]
					[a] Irbesartan HCT Winthrop 300/12.5 [WA]	[a] Irbesartan HCTZ AN 300/12.5 [EA]
					[a] Irbesartan HCTZ-GA 300/12.5 [EF]	[a] Irbesartan/HCTZ RBX 300/12.5 [RA]
					[a] KSART HCT 300/12.5 [RW]	[a] Terry White Chemists Irbesartan HCTZ [TW]
		[B]1.90	19.94	19.21	[a] Avapro HCT 300/12.5 [AV]	[a] Karvezide 300/12.5 [SW]

irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30

2136K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	18.98	20.15	[a] Abisart HCT 300/25 [AF]	[a] APO-Irbesartan HCTZ [TX]
					[a] Chem mart Irbesartan HCTZ [CH]	[a] Irbesartan HCT Actavis 300/25 [ED]
					[a] Irbesartan HCT GH 300/25 [GQ]	[a] Irbesartan/HCT Sandoz [SZ]
					[a] Irbesartan HCT Winthrop 300/25 [WA]	[a] Irbesartan HCTZ AN 300/25 [EA]
					[a] Irbesartan HCTZ-GA 300/25 [EF]	[a] Irbesartan/HCTZ RBX 300/25 [RA]
					[a] KSART HCT 300/25 [RW]	[a] Terry White Chemists Irbesartan HCTZ [TW]
		[B]1.90	20.88	20.15	[a] Avapro HCT 300/25 [AV]	[a] Karvezide 300/25 [SW]

▪ OLMESARTAN MEDOXOMIL + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension
Clinical criteria:
The treatment must not be for the initiation of anti-hypertensive therapy, AND
The condition must be inadequately controlled with an angiotensin II antagonist; OR
The condition must be inadequately controlled with a thiazide diuretic.

olmesartan medoxomil 20 mg + hydrochlorothiazide 12.5 mg tablet, 30

2161R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	20.25	21.42	Olmetec Plus [MK]

olmesartan medoxomil 40 mg + hydrochlorothiazide 12.5 mg tablet, 30

2166B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	29.20	30.37	Olmetec Plus [MK]

olmesartan medoxomil 40 mg + hydrochlorothiazide 25 mg tablet, 30

2170F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	31.04	32.21	Olmetec Plus [MK]

▪ TELMISARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy, AND

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a thiazide diuretic.

telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28

8622T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.20	16.37	[a] APO-Telmisartan HCTZ 40/12.5 [TX]	[a] Chem mart Telmisartan HCTZ 40/12.5 [CH]
						[a] Mizart HCT 40/12.5 mg [AF]	[a] Pritor Plus 40/12.5 mg [FI]
						[a] Telmigen HCT 40/12.5 [ED]	[a] Telmisartan HCT GH 40/12.5 [GQ]
						[a] Telmisartan/HCT Sandoz [SZ]	[a] Telmisartan HCTZ AN 40/12.5 [EA]
						[a] Teltartan HCT 40/12.5 [RW]	[a] Terry White Chemists Telmisartan HCTZ 40/12.5 [TW]
			[B]1.62	16.82	16.37	[a] Micardis Plus 40/12.5 mg [BY]	

telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28

8623W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.33	23.50	[a] APO-Telmisartan HCTZ 80/12.5 [TX]	[a] Chem mart Telmisartan HCTZ 80/12.5 [CH]
						[a] Mizart HCT 80/12.5 mg [AF]	[a] Pritor Plus 80/12.5 mg [FI]
						[a] Telmigen HCT 80/12.5 [ED]	[a] Telmisartan HCT GH 80/12.5 [GQ]
						[a] Telmisartan/HCT Sandoz [SZ]	[a] Telmisartan HCTZ AN 80/12.5 [EA]
						[a] Teltartan HCT 80/12.5 [RW]	[a] Terry White Chemists Telmisartan HCTZ 80/12.5 [TW]
			[B]1.62	23.95	23.50	[a] Micardis Plus 80/12.5 mg [BY]	

telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28

9381R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	23.40	24.57	[a] APO-Telmisartan HCTZ 80/25 [TX]	[a] Chem mart Telmisartan HCTZ 80/25 [CH]
						[a] Mizart HCT 80/25 mg [AF]	[a] Pritor Plus 80/25 mg [FI]
						[a] Telmigen HCT 80/25 [ED]	[a] Telmisartan HCT GH 80/25 [GQ]
						[a] Telmisartan/HCT Sandoz [SZ]	[a] Telmisartan HCTZ AN 80/25 [EA]
						[a] Teltartan HCT 80/25 [RW]	[a] Terry White Chemists Telmisartan HCTZ 80/25 [TW]
			[B]1.61	25.01	24.57	[a] Micardis Plus 80/25 mg [BY]	

▪ VALSARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy, AND

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a thiazide diuretic.

valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9373H NP	1	5	..	23.37	24.54	[a] APO-Valsartan HCTZ 160/12.5 [TX] [a] Dilart HCT 160/12.5 [AF]	[a] Co-Diovan 160/12.5 [NV]

valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9374J NP	1	5	..	24.88	26.05	[a] Co-Diovan 160/25 [NV]	[a] Dilart HCT 160/25 [AF]

valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9372G NP	1	5	..	20.84	22.01	[a] Co-Diovan 80/12.5 [NV]	[a] Dilart HCT 80/12.5 [AF]

▪ VALSARTAN + HYDROCHLOROTHIAZIDE

Note No applications for increased maximum quantities and/or repeats will be authorised for the tablets containing 320 mg valsartan.

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy, AND

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a thiazide diuretic.

valsartan 320 mg + hydrochlorothiazide 12.5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9481B NP	1	5	..	26.59	27.76	[a] APO-Valsartan HCTZ 320/12.5 [TX] [a] Dilart HCT 320/12.5 [AF]	[a] Co-Diovan 320/12.5 [NV]

valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9482C NP	1	5	..	28.11	29.28	[a] APO-Valsartan HCTZ 320/25 [TX] [a] Dilart HCT 320/25 [AF]	[a] Co-Diovan 320/25 [NV]

Angiotensin II antagonists and calcium channel blockers

▪ AMLODIPINE + VALSARTAN

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy, AND

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

amlodipine 10 mg + valsartan 160 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9377M NP	1	5	..	23.61	24.78	Exforge 10/160 [NV]

amlodipine 10 mg + valsartan 320 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5460J NP	1	5	..	26.84	28.01	Exforge 10/320 [NV]

amlodipine 5 mg + valsartan 160 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9376L NP	1	5	..	22.85	24.02	Exforge 5/160 [NV]

amlodipine 5 mg + valsartan 320 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5459H NP	1	5	..	26.07	27.24	Exforge 5/320 [NV]

amlodipine 5 mg + valsartan 80 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9375K NP	1	5	..	20.32	21.49	[a] Exforge 5/80 [NV]	[a] Valsartan/Amlodipine Sandoz 80/5 [NM]

▪ OLMESARTAN MEDOXOMIL + AMLODIPINE

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy, AND

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5292M NP	1	5	..	19.48	20.65	Sevikar 20/5 [MK]

olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5294P NP	1	5	..	29.26	30.43	Sevikar 40/10 [MK]

olmesartan medoxomil 40 mg + amlodipine 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5293N NP	1	5	..	28.44	29.61	Sevikar 40/5 [MK]

▪ TELMISARTAN + AMLODIPINE

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy, AND

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

telmisartan 40 mg + amlodipine 10 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8979N NP	1	5	..	15.77	16.94	[a] Pritor/Amlodipine [FI]
			[B]1.62	17.39	16.94	[a] Twynsta [BY]

telmisartan 40 mg + amlodipine 5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8978M NP	1	5	..	15.01	16.18	[a] Pritor/Amlodipine [FI]
			[B]1.61	16.62	16.18	[a] Twynsta [BY]

telmisartan 80 mg + amlodipine 10 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8981Q NP	1	5	..	22.58	23.75	[a] Pritor/Amlodipine [FI]
			[B]1.61	24.19	23.75	[a] Twynsta [BY]

telmisartan 80 mg + amlodipine 5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8980P NP	1	5	..	21.82	22.99	[a] Pritor/Amlodipine [FI]
			[B]1.61	23.43	22.99	[a] Twynsta [BY]

Angiotensin II antagonists, other combinations

▪ AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy, AND

The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5287G NP	1	5	..	25.13	26.30	Exforge HCT 10/160/12.5 [NV]

amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5288H NP	1	5	..	26.64	27.81	Exforge HCT 10/160/25 [NV]

amlodipine 10 mg + valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5289J NP	1	5	..	29.87	31.04	Exforge HCT 10/320/25 [NV]

amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5285E NP	1	5	..	24.37	25.54	[a] Exforge HCT 5/160/12.5 [NV]	[a] Valsartan/Amlodipine/HCT Sandoz 160/5/12.5 [NM]

amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5286F NP	1	5	..	25.88	27.05	Exforge HCT 5/160/25 [NV]

▪ OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE

Restricted benefit

Hypertension

Clinical criteria:

The treatment must not be for the initiation of anti-hypertensive therapy, AND

The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.

olmesartan medoxomil 20 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10005N NP	1	5	..	21.32	22.49	Sevikar HCT 20/5/12.5 [MK]

olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 12.5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2836G NP	1	5	..	31.10	32.27	Sevikar HCT 40/10/12.5 [MK]

olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 25 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2953K NP	1	5	..	32.93	34.10	Sevikar HCT 40/10/25 [MK]

olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2880N NP	1	5	..	30.28	31.45	Sevikar HCT 40/5/12.5 [MK]

olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 25 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2864R NP	1	5	..	32.12	33.29	Sevikar HCT 40/5/25 [MK]

▪ LIPID MODIFYING AGENTS

LIPID MODIFYING AGENTS, PLAIN

HMG CoA reductase inhibitors

▪ ATORVASTATIN

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

atorvastatin 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8213G NP	1	5	..	12.97	14.14	[a] APO-Atorvastatin [TX] [a] Atorvastatin AN [EA] [a] Atorvastatin Pfizer [FZ] [a] Atorvastatin SCP 10 [RZ] [a] Blooms the Chemist Atorvastatin [IB] [a] Lipitor [PF] [a] Terry White Chemists Atorvastatin [TW] [a] Trovas [RA]	[a] Atorvachol [ED] [a] Atorvastatin GH [GQ] [a] Atorvastatin Sandoz [SZ] [a] Atorvastatin SZ [HX] [a] Chem mart Atorvastatin [CH] [a] Lorstat 10 [AF] [a] Torvastat 10 [RW]

atorvastatin 20 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8214H NP	1	5	..	14.17	15.34	[a] APO-Atorvastatin [TX] [a] Atorvastatin AN [EA]	[a] Atorvachol [ED] [a] Atorvastatin GH [GQ]

						[a] Atorvastatin Pfizer [FZ] [a] Atorvastatin SCP 20 [RZ] [a] Blooms the Chemist Atorvastatin [IB] [a] Lipitor [PF] [a] Terry White Chemists Atorvastatin [TW] [a] Trovas [RA]	[a] Atorvastatin Sandoz [SZ] [a] Atorvastatin SZ [HX] [a] Chem mart Atorvastatin [CH] [a] Lorstat 20 [AF] [a] Torvastat 20 [RW]

atorvastatin 40 mg tablet, 30

8215J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.71	16.88	[a] APO-Atorvastatin [TX] [a] Atorvastatin AN [EA] [a] Atorvastatin Pfizer [FZ] [a] Atorvastatin SCP 40 [RZ] [a] Blooms the Chemist Atorvastatin [IB] [a] Lipitor [PF] [a] Terry White Chemists Atorvastatin [TW] [a] Trovas [RA]	[a] Atorvachol [ED] [a] Atorvastatin GH [GQ] [a] Atorvastatin Sandoz [SZ] [a] Atorvastatin SZ [HX] [a] Chem mart Atorvastatin [CH] [a] Lorstat 40 [AF] [a] Torvastat 40 [RW]

atorvastatin 80 mg tablet, 30

8521L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.98	19.15	[a] APO-Atorvastatin [TX] [a] Atorvastatin AN [EA] [a] Atorvastatin Pfizer [FZ] [a] Atorvastatin SCP 80 [RZ] [a] Blooms the Chemist Atorvastatin [IB] [a] Lipitor [PF] [a] Terry White Chemists Atorvastatin [TW] [a] Trovas [RA]	[a] Atorvachol [ED] [a] Atorvastatin GH [GQ] [a] Atorvastatin Sandoz [SZ] [a] Atorvastatin SZ [HX] [a] Chem mart Atorvastatin [CH] [a] Lorstat 80 [AF] [a] Torvastat 80 [RW]

▪ ATORVASTATIN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

Clinical criteria:

Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

atorvastatin 10 mg tablet, 30

9230T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	12.97	14.14	[a] APO-Atorvastatin [TX] [a] Atorvastatin AN [EA] [a] Atorvastatin Pfizer [FZ] [a] Atorvastatin SCP 10 [RZ] [a] Blooms the Chemist Atorvastatin [IB] [a] Lipitor [PF] [a] Terry White Chemists Atorvastatin [TW] [a] Trovas [RA]	[a] Atorvachol [ED] [a] Atorvastatin GH [GQ] [a] Atorvastatin Sandoz [SZ] [a] Atorvastatin SZ [HX] [a] Chem mart Atorvastatin [CH] [a] Lorstat 10 [AF] [a] Torvastat 10 [RW]

atorvastatin 20 mg tablet, 30

9231W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	14.17	15.34	[a] APO-Atorvastatin [TX] [a] Atorvastatin AN [EA] [a] Atorvastatin Pfizer [FZ] [a] Atorvastatin SCP 20 [RZ] [a] Blooms the Chemist Atorvastatin [IB] [a] Lipitor [PF] [a] Terry White Chemists Atorvastatin [TW] [a] Trovas [RA]	[a] Atorvachol [ED] [a] Atorvastatin GH [GQ] [a] Atorvastatin Sandoz [SZ] [a] Atorvastatin SZ [HX] [a] Chem mart Atorvastatin [CH] [a] Lorstat 20 [AF] [a] Torvastat 20 [RW]

atorvastatin 40 mg tablet, 30

9232X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	15.71	16.88	[a] APO-Atorvastatin [TX] [a] Atorvastatin AN [EA] [a] Atorvastatin Pfizer [FZ] [a] Atorvastatin SCP 40 [RZ] [a] Blooms the Chemist Atorvastatin [IB] [a] Lipitor [PF] [a] Terry White Chemists Atorvastatin [TW] [a] Trovas [RA]	[a] Atorvachol [ED] [a] Atorvastatin GH [GQ] [a] Atorvastatin Sandoz [SZ] [a] Atorvastatin SZ [HX] [a] Chem mart Atorvastatin [CH] [a] Lorstat 40 [AF] [a] Torvastat 40 [RW]

atorvastatin 80 mg tablet, 30

9233Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	17.98	19.15	[a] APO-Atorvastatin [TX] [a] Atorvastatin AN [EA] [a] Atorvastatin Pfizer [FZ] [a] Atorvastatin SCP 80 [RZ] [a] Blooms the Chemist Atorvastatin [IB] [a] Lipitor [PF] [a] Terry White Chemists Atorvastatin [TW] [a] Trovas [RA]	[a] Atorvachol [ED] [a] Atorvastatin GH [GQ] [a] Atorvastatin Sandoz [SZ] [a] Atorvastatin SZ [HX] [a] Chem mart Atorvastatin [CH] [a] Lorstat 80 [AF] [a] Torvastat 80 [RW]

▪ FLUVASTATIN

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

fluvastatin 80 mg tablet: modified release, 28

2863Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	44.92	38.30	Lescol XL [NV]

▪ FLUVASTATIN

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

Clinical criteria:

Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

fluvastatin 80 mg tablet: modified release, 28

9236D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	11	..	44.92	38.30	Lescol XL [NV]

▪ PRAVASTATIN

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

pravastatin sodium 10 mg tablet, 30

2833D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.27	13.44	[a] APO-Pravastatin [TX] [a] Chem mart Pravastatin [CH] [a] Lipostat 10 [RF] [a] Pravastatin AN [EA] [a] Pravastatin generichealth [GQ] [a] Terry White Chemists Pravastatin [TW]	[a] Auro-Pravastatin 10 [DO] [a] Cholstat 10 [AF] [a] Pharmacor Pravastat 10 [CR] [a] Pravastatin-GA 10 [ED] [a] Pravastatin Sandoz [SZ]
			[B]1.03	13.30	13.44	[a] Pravachol [RW]	

pravastatin sodium 20 mg tablet, 30

2834E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.36	14.53	[a] APO-Pravastatin [TX] [a] Chem mart Pravastatin [CH] [a] Cholvastin [RA] [a] Pharmacor Pravastat 20 [CR] [a] Pravastatin-GA 20 [ED]	[a] Auro-Pravastatin 20 [DO] [a] Cholstat 20 [AF] [a] Lipostat 20 [RF] [a] Pravastatin AN [EA] [a] Pravastatin generichealth [GQ]

						[a] Pravastatin Sandoz [SZ]	[a] Terry White Chemists Pravastatin [TW]
			[B]1.03	14.39	14.53	[a] Pravachol [RW]	

pravastatin sodium 40 mg tablet, 30

8197K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.98	16.15	[a] APO-Pravastatin [TX]	[a] Auro-Pravastatin 40 [DO]
						[a] Chem mart Pravastatin [CH]	[a] Cholstat 40 [AF]
						[a] Cholvastin [RA]	[a] Lipostat 40 [RF]
						[a] Pharmacor Pravastat 40 [CR]	[a] Pravastatin AN [EA]
						[a] Pravastatin-GA 40 [ED]	[a] Pravastatin generichealth [GQ]
						[a] Pravastatin Sandoz [SZ]	[a] Terry White Chemists Pravastatin [TW]
			[B]1.08	16.06	16.15	[a] Pravachol [RW]	

pravastatin sodium 80 mg tablet, 30

8829Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.43	18.60	[a] APO-Pravastatin [TX]	[a] Auro-Pravastatin 80 [DO]
						[a] Chem mart Pravastatin [CH]	[a] Lipostat 80 [RF]
						[a] Pravastatin AN [EA]	[a] Pravastatin-GA 80 [ED]
						[a] Pravastatin generichealth [GQ]	[a] Pravastatin Sandoz [SZ]
						[a] Terry White Chemists Pravastatin [TW]	
			[B]1.10	18.53	18.60	[a] Pravachol [RW]	

▪ PRAVASTATIN

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

Clinical criteria:

Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

pravastatin sodium 10 mg tablet, 30

9237E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	12.27	13.44	[a] APO-Pravastatin [TX]	[a] Auro-Pravastatin 10 [DO]
						[a] Chem mart Pravastatin [CH]	[a] Cholstat 10 [AF]
						[a] Lipostat 10 [RF]	[a] Pharmacor Pravastat 10 [CR]
						[a] Pravastatin AN [EA]	[a] Pravastatin-GA 10 [ED]
						[a] Pravastatin generichealth [GQ]	[a] Pravastatin Sandoz [SZ]
						[a] Terry White Chemists Pravastatin [TW]	
			[B]1.03	13.30	13.44	[a] Pravachol [RW]	

pravastatin sodium 20 mg tablet, 30

9238F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	13.36	14.53	[a] APO-Pravastatin [TX]	[a] Auro-Pravastatin 20 [DO]
						[a] Chem mart Pravastatin [CH]	[a] Cholstat 20 [AF]
						[a] Cholvastin [RA]	[a] Lipostat 20 [RF]
						[a] Pharmacor Pravastat 20 [CR]	[a] Pravastatin AN [EA]
						[a] Pravastatin-GA 20 [ED]	[a] Pravastatin generichealth [GQ]
						[a] Pravastatin Sandoz [SZ]	[a] Terry White Chemists Pravastatin [TW]
			[B]1.03	14.39	14.53	[a] Pravachol [RW]	

pravastatin sodium 40 mg tablet, 30

9239G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	14.98	16.15	[a] APO-Pravastatin [TX]	[a] Auro-Pravastatin 40 [DO]
						[a] Chem mart Pravastatin [CH]	[a] Cholstat 40 [AF]
						[a] Cholvastin [RA]	[a] Lipostat 40 [RF]
						[a] Pharmacor Pravastat 40 [CR]	[a] Pravastatin AN [EA]
						[a] Pravastatin-GA 40 [ED]	[a] Pravastatin generichealth [GQ]
						[a] Pravastatin Sandoz [SZ]	[a] Terry White Chemists Pravastatin [TW]
			[B]1.08	16.06	16.15	[a] Pravachol [RW]	

pravastatin sodium 80 mg tablet, 30

9240H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	17.43	18.60	[a] APO-Pravastatin [TX]	[a] Auro-Pravastatin 80 [DO]

				[a] Chem mart Pravastatin [CH] [a] Pravastatin AN [EA] [a] Pravastatin generichealth [GQ] [a] Terry White Chemists Pravastatin [TW]	[a] Lipostat 80 [RF] [a] Pravastatin-GA 80 [ED] [a] Pravastatin Sandoz [SZ]
	[B]1.10	18.53	18.60	[a] Pravachol [RW]	

▪ ROSUVASTATIN

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

rosuvastatin 10 mg tablet, 30

2628H

Max.Qty	Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.25	22.42	[a] APO-Rosuvastatin [TX] [a] Cavstat [AF] [a] Crestor [AP] [a] Rosuvastatin Actavis 10 [ED] [a] Rosuvastatin-DRLA [RI] [a] Terry White Chemists Rosuvastatin [TW]	[a] Blooms the Chemist Rosuvastatin [IB] [a] Chem mart Rosuvastatin [CH] [a] Crosuva 10 [ZP] [a] Rosuvastatin AMNEAL [EF] [a] Rosuvastatin GH [GQ]

rosuvastatin 20 mg tablet, 30

2574L

Max.Qty	Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	25.83	27.00	[a] APO-Rosuvastatin [TX] [a] Cavstat [AF] [a] Crestor [AP] [a] Rosuvastatin Actavis 20 [ED] [a] Rosuvastatin-DRLA [RI] [a] Terry White Chemists Rosuvastatin [TW]	[a] Blooms the Chemist Rosuvastatin [IB] [a] Chem mart Rosuvastatin [CH] [a] Crosuva 20 [ZP] [a] Rosuvastatin AMNEAL [EF] [a] Rosuvastatin GH [GQ]

rosuvastatin 40 mg tablet, 30

2594M

Max.Qty	Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	32.40	33.57	[a] APO-Rosuvastatin [TX] [a] Cavstat [AF] [a] Crestor [AP] [a] Rosuvastatin Actavis 40 [ED] [a] Rosuvastatin-DRLA [RI] [a] Terry White Chemists Rosuvastatin [TW]	[a] Blooms the Chemist Rosuvastatin [IB] [a] Chem mart Rosuvastatin [CH] [a] Crosuva 40 [ZP] [a] Rosuvastatin AMNEAL [EF] [a] Rosuvastatin GH [GQ]

rosuvastatin 5 mg tablet, 30

2606E

Max.Qty	Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.80	18.97	[a] APO-Rosuvastatin [TX] [a] Cavstat [AF] [a] Crestor [AP] [a] Rosuvastatin Actavis 5 [ED] [a] Rosuvastatin-DRLA [RI] [a] Terry White Chemists Rosuvastatin [TW]	[a] Blooms the Chemist Rosuvastatin [IB] [a] Chem mart Rosuvastatin [CH] [a] Crosuva 5 [ZP] [a] Rosuvastatin AMNEAL [EF] [a] Rosuvastatin GH [GQ]

▪ ROSUVASTATIN

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

Clinical criteria:

The treatment must not be prescribed for hypercholesterolaemia if the patient has heterozygous familial hypercholesterolaemia.

rosuvastatin 10 mg tablet, 30

9043Y

Max.Qty	Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.25	22.42	[a] APO-Rosuvastatin [TX] [a] Cavstat [AF] [a] Crestor [AP] [a] Rostor 10 [DO] [a] Rosuvastatin AMNEAL [EF] [a] Rosuvastatin-DRLA [RI]	[a] Blooms the Chemist Rosuvastatin [IB] [a] Chem mart Rosuvastatin [CH] [a] Crosuva 10 [ZP] [a] Rosuvastatin Actavis 10 [ED] [a] Rosuvastatin AN [EA] [a] Rosuvastatin GH [GQ]

						[a] Rosuvastatin RBX [RA] [a] Terry White Chemists Rosuvastatin [TW]	[a] Rosuvastatin Sandoz [SZ]

rosuvastatin 20 mg tablet, 30

9044B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	25.83	27.00	[a] APO-Rosuvastatin [TX] [a] Cavstat [AF] [a] Crestor [AP] [a] Rostor 20 [DO] [a] Rosuvastatin AMNEAL [EF] [a] Rosuvastatin-DRLA [RI] [a] Rosuvastatin RBX [RA] [a] Terry White Chemists Rosuvastatin [TW]	[a] Blooms the Chemist Rosuvastatin [IB] [a] Chem mart Rosuvastatin [CH] [a] Crosuva 20 [ZP] [a] Rosuvastatin Actavis 20 [ED] [a] Rosuvastatin AN [EA] [a] Rosuvastatin GH [GQ] [a] Rosuvastatin Sandoz [SZ]

rosuvastatin 40 mg tablet, 30

9045C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	32.40	33.57	[a] APO-Rosuvastatin [TX] [a] Cavstat [AF] [a] Crestor [AP] [a] Rostor 40 [DO] [a] Rosuvastatin AMNEAL [EF] [a] Rosuvastatin-DRLA [RI] [a] Rosuvastatin RBX [RA] [a] Terry White Chemists Rosuvastatin [TW]	[a] Blooms the Chemist Rosuvastatin [IB] [a] Chem mart Rosuvastatin [CH] [a] Crosuva 40 [ZP] [a] Rosuvastatin Actavis 40 [ED] [a] Rosuvastatin AN [EA] [a] Rosuvastatin GH [GQ] [a] Rosuvastatin Sandoz [SZ]

rosuvastatin 5 mg tablet, 30

9042X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.80	18.97	[a] APO-Rosuvastatin [TX] [a] Cavstat [AF] [a] Crestor [AP] [a] Rostor 5 [DO] [a] Rosuvastatin AMNEAL [EF] [a] Rosuvastatin-DRLA [RI] [a] Rosuvastatin RBX [RA] [a] Terry White Chemists Rosuvastatin [TW]	[a] Blooms the Chemist Rosuvastatin [IB] [a] Chem mart Rosuvastatin [CH] [a] Crosuva 5 [ZP] [a] Rosuvastatin Actavis 5 [ED] [a] Rosuvastatin AN [EA] [a] Rosuvastatin GH [GQ] [a] Rosuvastatin Sandoz [SZ]

▪ ROSUVASTATIN

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

Clinical criteria:

Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

rosuvastatin 10 mg tablet, 30

2584B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	21.25	22.42	[a] APO-Rosuvastatin [TX] [a] Cavstat [AF] [a] Crestor [AP] [a] Rosuvastatin Actavis 10 [ED] [a] Rosuvastatin-DRLA [RI] [a] Terry White Chemists Rosuvastatin [TW]	[a] Blooms the Chemist Rosuvastatin [IB] [a] Chem mart Rosuvastatin [CH] [a] Crosuva 10 [ZP] [a] Rosuvastatin AMNEAL [EF] [a] Rosuvastatin GH [GQ]

rosuvastatin 20 mg tablet, 30

2609H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	25.83	27.00	[a] APO-Rosuvastatin [TX] [a] Cavstat [AF] [a] Crestor [AP] [a] Rosuvastatin Actavis 20 [ED]	[a] Blooms the Chemist Rosuvastatin [IB] [a] Chem mart Rosuvastatin [CH] [a] Crosuva 20 [ZP] [a] Rosuvastatin AMNEAL [EF]

						[a] Rosuvastatin-DRLA [RI] [a] Terry White Chemists Rosuvastatin [TW]	[a] Rosuvastatin GH [GQ]

rosuvastatin 40 mg tablet, 30

2636R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	32.40	33.57	[a] APO-Rosuvastatin [TX] [a] Cavstat [AF] [a] Crestor [AP] [a] Rosuvastatin Actavis 40 [ED] [a] Rosuvastatin-DRLA [RI] [a] Terry White Chemists Rosuvastatin [TW]	[a] Blooms the Chemist Rosuvastatin [IB] [a] Chem mart Rosuvastatin [CH] [a] Crosuva 40 [ZP] [a] Rosuvastatin AMNEAL [EF] [a] Rosuvastatin GH [GQ]

rosuvastatin 5 mg tablet, 30

2590H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	17.80	18.97	[a] APO-Rosuvastatin [TX] [a] Cavstat [AF] [a] Crestor [AP] [a] Rosuvastatin Actavis 5 [ED] [a] Rosuvastatin-DRLA [RI] [a] Terry White Chemists Rosuvastatin [TW]	[a] Blooms the Chemist Rosuvastatin [IB] [a] Chem mart Rosuvastatin [CH] [a] Crosuva 5 [ZP] [a] Rosuvastatin AMNEAL [EF] [a] Rosuvastatin GH [GQ]

▪ ROSUVASTATIN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

Clinical criteria:

Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements, AND

The treatment must not be prescribed for hypercholesterolaemia if the patient has heterozygous familial hypercholesterolaemia.

rosuvastatin 10 mg tablet, 30

3403D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	21.25	22.42	[a] APO-Rosuvastatin [TX] [a] Cavstat [AF] [a] Crestor [AP] [a] Rostor 10 [DO] [a] Rosuvastatin AMNEAL [EF] [a] Rosuvastatin-DRLA [RI] [a] Rosuvastatin RBX [RA] [a] Terry White Chemists Rosuvastatin [TW]	[a] Blooms the Chemist Rosuvastatin [IB] [a] Chem mart Rosuvastatin [CH] [a] Crosuva 10 [ZP] [a] Rosuvastatin Actavis 10 [ED] [a] Rosuvastatin AN [EA] [a] Rosuvastatin GH [GQ] [a] Rosuvastatin Sandoz [SZ]

rosuvastatin 20 mg tablet, 30

3404E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	25.83	27.00	[a] APO-Rosuvastatin [TX] [a] Cavstat [AF] [a] Crestor [AP] [a] Rostor 20 [DO] [a] Rosuvastatin AMNEAL [EF] [a] Rosuvastatin-DRLA [RI] [a] Rosuvastatin RBX [RA] [a] Terry White Chemists Rosuvastatin [TW]	[a] Blooms the Chemist Rosuvastatin [IB] [a] Chem mart Rosuvastatin [CH] [a] Crosuva 20 [ZP] [a] Rosuvastatin Actavis 20 [ED] [a] Rosuvastatin AN [EA] [a] Rosuvastatin GH [GQ] [a] Rosuvastatin Sandoz [SZ]

rosuvastatin 40 mg tablet, 30

3405F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	32.40	33.57	[a] APO-Rosuvastatin [TX] [a] Cavstat [AF] [a] Crestor [AP] [a] Rostor 40 [DO]	[a] Blooms the Chemist Rosuvastatin [IB] [a] Chem mart Rosuvastatin [CH] [a] Crosuva 40 [ZP] [a] Rosuvastatin Actavis 40 [ED]

						[a] Rosuvastatin AMNEAL [EF]	[a] Rosuvastatin AN [EA]
						[a] Rosuvastatin-DRLA [RI]	[a] Rosuvastatin GH [GQ]
						[a] Rosuvastatin RBX [RA]	[a] Rosuvastatin Sandoz [SZ]
						[a] Terry White Chemists Rosuvastatin [TW]	

rosuvastatin 5 mg tablet, 30

3402C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	17.80	18.97	[a] APO-Rosuvastatin [TX]	[a] Blooms the Chemist Rosuvastatin [IB]
						[a] Cavstat [AF]	[a] Chem mart Rosuvastatin [CH]
						[a] Crestor [AP]	[a] Crosuva 5 [ZP]
						[a] Rostor 5 [DO]	[a] Rosuvastatin Actavis 5 [ED]
						[a] Rosuvastatin AMNEAL [EF]	[a] Rosuvastatin AN [EA]
						[a] Rosuvastatin-DRLA [RI]	[a] Rosuvastatin GH [GQ]
						[a] Rosuvastatin RBX [RA]	[a] Rosuvastatin Sandoz [SZ]
						[a] Terry White Chemists Rosuvastatin [TW]	

▪ SIMVASTATIN

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

simvastatin 10 mg tablet, 30

2011W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	11.90	13.07	[a] APO-Simvastatin [TX]	[a] Auro-Simvastatin 10 [DO]
						[a] Chem mart Simvastatin [CH]	[a] GenRx Simvastatin [GX]
						[a] Ransim [RA]	[a] Simvacor 10 [CR]
						[a] Simvar 10 [RW]	[a] Simvastatin AN [EA]
						[a] Simvastatin-GA 10 [ED]	[a] Simvastatin generichealth [GQ]
						[a] Simvastatin Sandoz [SZ]	[a] Terry White Chemists Simvastatin [TW]
						[a] Zimstat [AF]	
			[B]5.00	16.90	13.07	[a] Lipex 10 [FR]	[a] Zocor [MK]

simvastatin 20 mg tablet, 30

2012X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.57	13.74	[a] APO-Simvastatin [TX]	[a] Auro-Simvastatin 20 [DO]
						[a] Chem mart Simvastatin [CH]	[a] Ransim [RA]
						[a] Simvacor 20 [CR]	[a] Simvar 20 [RW]
						[a] Simvastatin AN [EA]	[a] Simvastatin-GA 20 [ED]
						[a] Simvastatin generichealth [GQ]	[a] Simvastatin Sandoz [SZ]
						[a] Terry White Chemists Simvastatin [TW]	[a] Zimstat [AF]
			[B]5.00	17.57	13.74	[a] Lipex 20 [FR]	[a] Zocor [MK]

simvastatin 40 mg tablet, 30

8173E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.51	14.68	[a] APO-Simvastatin [TX]	[a] Auro-Simvastatin 40 [DO]
						[a] Chem mart Simvastatin [CH]	[a] Ransim [RA]
						[a] Simvacor 40 [CR]	[a] Simvar 40 [RW]
						[a] Simvastatin AN [EA]	[a] Simvastatin-GA 40 [ED]
						[a] Simvastatin generichealth [GQ]	[a] Simvastatin Sandoz [SZ]
						[a] Terry White Chemists Simvastatin [TW]	[a] Zimstat [AF]
			[B]5.00	18.51	14.68	[a] Lipex 40 [FR]	[a] Zocor [MK]

simvastatin 5 mg tablet, 30

2013Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	11.50	12.67	[a] Simvastatin Sandoz [SZ]	[a] Zimstat [AF]

simvastatin 80 mg tablet, 30

8313M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.85	16.02	[a] APO-Simvastatin [TX]	[a] Auro-Simvastatin 80 [DO]
						[a] Chem mart Simvastatin [CH]	[a] Ransim [RA]
						[a] Simvacor 80 [CR]	[a] Simvar 80 [RW]
						[a] Simvastatin AN [EA]	[a] Simvastatin-GA 80 [ED]

					[a] Simvastatin generichealth [GQ]	[a] Simvastatin Sandoz [SZ]
					[a] Terry White Chemists Simvastatin [TW]	[a] Zimstat [AF]
		[B]5.00	19.85	16.02	[a] Lipex 80 [FR]	[a] Zocor [MK]

▪ SIMVASTATIN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

Clinical criteria:

Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

simvastatin 10 mg tablet, 30

9242K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	11.90	13.07	[a] APO-Simvastatin [TX]	[a] Auro-Simvastatin 10 [DO]
						[a] Chem mart Simvastatin [CH]	[a] GenRx Simvastatin [GX]
						[a] Ransim [RA]	[a] Simvacor 10 [CR]
						[a] Simvar 10 [RW]	[a] Simvastatin AN [EA]
						[a] Simvastatin-GA 10 [ED]	[a] Simvastatin generichealth [GQ]
						[a] Simvastatin Sandoz [SZ]	[a] Terry White Chemists Simvastatin [TW]
						[a] Zimstat [AF]	
			[B]5.00	16.90	13.07	[a] Lipex 10 [FR]	[a] Zocor [MK]

simvastatin 20 mg tablet, 30

9243L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	12.57	13.74	[a] APO-Simvastatin [TX]	[a] Auro-Simvastatin 20 [DO]
						[a] Chem mart Simvastatin [CH]	[a] Ransim [RA]
						[a] Simvacor 20 [CR]	[a] Simvar 20 [RW]
						[a] Simvastatin AN [EA]	[a] Simvastatin-GA 20 [ED]
						[a] Simvastatin generichealth [GQ]	[a] Simvastatin Sandoz [SZ]
						[a] Terry White Chemists Simvastatin [TW]	[a] Zimstat [AF]
			[B]5.00	17.57	13.74	[a] Lipex 20 [FR]	[a] Zocor [MK]

simvastatin 40 mg tablet, 30

9244M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	13.51	14.68	[a] APO-Simvastatin [TX]	[a] Auro-Simvastatin 40 [DO]
						[a] Chem mart Simvastatin [CH]	[a] Ransim [RA]
						[a] Simvacor 40 [CR]	[a] Simvar 40 [RW]
						[a] Simvastatin AN [EA]	[a] Simvastatin-GA 40 [ED]
						[a] Simvastatin generichealth [GQ]	[a] Simvastatin Sandoz [SZ]
						[a] Terry White Chemists Simvastatin [TW]	[a] Zimstat [AF]
			[B]5.00	18.51	14.68	[a] Lipex 40 [FR]	[a] Zocor [MK]

simvastatin 5 mg tablet, 30

9241J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	11.50	12.67	[a] Simvastatin Sandoz [SZ]	[a] Zimstat [AF]

simvastatin 80 mg tablet, 30

9245N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	14.85	16.02	[a] APO-Simvastatin [TX]	[a] Auro-Simvastatin 80 [DO]
						[a] Chem mart Simvastatin [CH]	[a] Ransim [RA]
						[a] Simvacor 80 [CR]	[a] Simvar 80 [RW]
						[a] Simvastatin AN [EA]	[a] Simvastatin-GA 80 [ED]
						[a] Simvastatin generichealth [GQ]	[a] Simvastatin Sandoz [SZ]
						[a] Terry White Chemists Simvastatin [TW]	[a] Zimstat [AF]
			[B]5.00	19.85	16.02	[a] Lipex 80 [FR]	[a] Zocor [MK]

Fibrates

▪ FENOFIBRATE

Note The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

fenofibrate 145 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9023X NP	1	5	..	39.71	38.30	Lipidil [GO]

fenofibrate 48 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9022W NP	1	5	..	29.93	31.10	Lipidil [GO]

▪ FENOFIBRATE

Note The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

Clinical criteria:

Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

fenofibrate 145 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9247Q	1	11	..	39.71	38.30	Lipidil [GO]

fenofibrate 48 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9246P	1	11	..	29.93	31.10	Lipidil [GO]

▪ GEMFIBROZIL

Note The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

gemfibrozil 600 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1453L NP	1	5	..	20.32	21.49	[a] Ausgem [RW]	[a] Lipigem [AF]

▪ GEMFIBROZIL

Note The risk of serious muscle toxicity is increased if this drug is used concomitantly with HMG CoA reductase inhibitors or other fibrates. Such combination therapy should be used with caution in patients with severe combined dyslipidaemia and high cardiovascular risk without any history of muscular disease and patients monitored closely for chronic signs of muscle toxicity.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

Clinical criteria:

Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

gemfibrozil 600 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9248R	1	11	..	20.32	21.49	[a] Ausgem [RW]	[a] Lipigem [AF]

Bile acid sequestrants

▪ CHOLESTYRAMINE

cholestyramine 4 g oral liquid: powder for, 50 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2967E NP	2	5	..	*67.03	38.30	Questran Lite [QA]

▪ CHOLESTYRAMINE

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

Restricted benefit

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

cholestyramine 4 g oral liquid: powder for, 50 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9249T	2	11	..	*67.03	38.30	Questran Lite [QA]

▪ COLESTIPOL HYDROCHLORIDE

colestipol hydrochloride 5 g granules, 120 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1224K NP	‡1	5	..	78.32	38.30	Colestid [PF]

▪ COLESTIPOL HYDROCHLORIDE

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

Restricted benefit

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

colestipol hydrochloride 5 g granules, 120 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9250W	‡1	11	..	78.32	38.30	Colestid [PF]

Other lipid modifying agents

▪ EZETIMIBE

Note Continuing Therapy Only:

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

Authority required (STREAMLINED)

5537

Hypercholesterolaemia

Clinical criteria:

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

The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), AND

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

Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

5543

Hypercholesterolaemia

Clinical criteria:

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

The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), AND

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

Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

5538

Hypercholesterolaemia

Clinical criteria:

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

The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), AND

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

Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

5544

Hypercholesterolaemia

Clinical criteria:

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

The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), AND

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

Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

5594

Hypercholesterolaemia

Clinical criteria:

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

The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), AND

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

Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

5586

Hypercholesterolaemia

Clinical criteria:

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

The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), AND

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

Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

5575

Hypercholesterolaemia

Clinical criteria:

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

The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), AND

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

Patient must have hypertension.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

5576

Hypercholesterolaemia

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, AND

Patient must be one in whom treatment with an HMG CoA reductase inhibitor (statin) is contraindicated.

Authority required (STREAMLINED)

5562

Hypercholesterolaemia

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, AND

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

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

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

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Authority required (STREAMLINED)

5563

Homozygous sitosterolaemia

Authority required (STREAMLINED)

5577

Hypercholesterolaemia

Clinical criteria:

Patient must have homozygous familial hypercholesterolaemia, AND

Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, AND

The treatment must be co-administered with an HMG CoA reductase inhibitor (statin).

ezetimibe 10 mg tablet, 30

8757X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	66.17	38.30	Ezetrol [MK]

LIPID MODIFYING AGENTS, COMBINATIONS

HMG CoA reductase inhibitors in combination with other lipid modifying agents

▪ EZETIMIBE + ATORVASTATIN

Note Continuing Therapy Only:

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

Authority required (STREAMLINED)

4068

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4085

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4086

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4069

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4096

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4120

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be

documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

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

Authority required (STREAMLINED)

4121

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have hypertension.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4097

Hypercholesterolaemia

Clinical criteria:

Patient must have homozygous familial hypercholesterolaemia, AND

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

ezetimibe 10 mg + atorvastatin 20 mg tablet, 30

10393B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	69.92	38.30	Atozet [MK]

ezetimibe 10 mg + atorvastatin 40 mg tablet, 30

10377E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	71.46	38.30	Atozet [MK]

ezetimibe 10 mg + atorvastatin 80 mg tablet, 30

10376D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	73.73	38.30	Atozet [MK]

▪ EZETIMIBE + ATORVASTATIN

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

Authority required (STREAMLINED)

4068

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4085

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4086

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4069

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4096

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4120

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4121

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have hypertension.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4097

Hypercholesterolaemia

Clinical criteria:

Patient must have homozygous familial hypercholesterolaemia, AND

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

Authority required (STREAMLINED)

4353

Hypercholesterolaemia

Clinical criteria:

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

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

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

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

ezetimibe 10 mg + atorvastatin 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10392Y NP	1	5	..	68.72	38.30	Atozet [MK]

▪ EZETIMIBE + SIMVASTATIN

Note Continuing Therapy Only:

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

Authority required (STREAMLINED)

4068

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4085

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4086

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4069

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4096

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4120

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

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

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be

documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4121

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have hypertension.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4097

Hypercholesterolaemia

Clinical criteria:

Patient must have homozygous familial hypercholesterolaemia, AND

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

ezetimibe 10 mg + simvastatin 40 mg tablet, 30

8881K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	69.25	38.30	Vytorin [MK]

ezetimibe 10 mg + simvastatin 80 mg tablet, 30

8882L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	70.60	38.30	Vytorin [MK]

▪ EZETIMIBE + SIMVASTATIN

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

Authority required (STREAMLINED)

4068

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4085

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4086

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4069

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4096

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4120

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4121

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have hypertension.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4097

Hypercholesterolaemia

Clinical criteria:

Patient must have homozygous familial hypercholesterolaemia, AND

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

Authority required (STREAMLINED)

4147

Hypercholesterolaemia

Clinical criteria:

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

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

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

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

ezetimibe 10 mg + simvastatin 10 mg tablet, 30

9483D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	67.65	38.30	Vytorin [MK]

ezetimibe 10 mg + simvastatin 20 mg tablet, 30

9484E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	68.32	38.30	Vytorin [MK]

▪ ROSUVASTATIN (&) EZETIMIBE

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

Authority required (STREAMLINED)

4068

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4085

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4086

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4069

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4096

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4120

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4121

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have hypertension.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4097

Hypercholesterolaemia

Clinical criteria:

Patient must have homozygous familial hypercholesterolaemia, AND

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

rosuvastatin 10 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack

10208G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	70.30	38.30	Rosuzet Composite Pack [MK]

rosuvastatin 20 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack

10201X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	71.99	38.30	Rosuzet Composite Pack [MK]

rosuvastatin 40 mg tablet [30] (&) ezetimibe 10 mg tablet [30 tablets], 1 pack

10207F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	74.48	38.30	Rosuzet Composite Pack [MK]

▪ ROSUVASTATIN (&) EZETIMIBE

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

Authority required (STREAMLINED)

4068

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4085

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4086

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4069

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4096

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

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

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and

exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4120

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4121

Hypercholesterolaemia

Clinical criteria:

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

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

Patient must have hypertension.

Inadequate control with a statin is defined as follows:

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

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

Authority required (STREAMLINED)

4097

Hypercholesterolaemia

Clinical criteria:

Patient must have homozygous familial hypercholesterolaemia, AND

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

Authority required (STREAMLINED)

4147

Hypercholesterolaemia

Clinical criteria:

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

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

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

(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

rosuvastatin 5 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack

10204C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	68.98	38.30	Rosuzet Composite Pack [MK]

HMG CoA reductase inhibitors, other combinations

▪ AMLODIPINE + ATORVASTATIN

Restricted benefit
Hypertension
Clinical criteria:
Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, AND
Patient must be currently receiving treatment with a dihydropyridine calcium channel blocker.

Restricted benefit
Angina
Clinical criteria:
Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, AND
Patient must be currently receiving treatment with a dihydropyridine calcium channel blocker.

Restricted benefit
Hypertension
Clinical criteria:
Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, AND
Patient must be one in whom blood pressure is inadequately controlled with other classes of antihypertensive agents, AND
The treatment must be appropriate for use as adjunctive therapy with a dihydropyridine calcium channel blocker.

Restricted benefit
Angina
Clinical criteria:
Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, AND
Patient must have angina which is inadequately controlled with other classes of anti-anginal agents, AND
The treatment must be appropriate for use as adjunctive therapy with a dihydropyridine calcium channel blocker.

Restricted benefit
Hypertension
Clinical criteria:
Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, AND
Patient must be intolerant of the side effects of other classes of antihypertensive agents, AND
Patient must be one in whom replacement therapy with a dihydropyridine calcium channel blocker would be appropriate.

Restricted benefit
Angina
Clinical criteria:
Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, AND
Patient must be intolerant of the side effects of other classes of anti-anginal agents, AND
Patient must be one in whom replacement therapy with a dihydropyridine calcium channel blocker would be appropriate.

amlodipine 10 mg + atorvastatin 10 mg tablet, 30

9053L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.86	16.03	[a] APO-Amlodipine/Atorvastatin 10/10 [TX]	[a] Blooms the Chemist Amlodipine/Atorvastatin 10/10 [IB]
						[a] Cadatin 10/10 [FZ]	[a] Cadivast 10/10 [AF]
						[a] Caduet 10/10 [PF]	[a] Chem mart Amlodipine/Atorvastatin 10/10 [CH]
						[a] Terry White Chemists Amlodipine/Atorvastatin 10/10 [TW]	

amlodipine 10 mg + atorvastatin 20 mg tablet, 30

9054M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.06	17.23	[a] APO-Amlodipine/Atorvastatin 10/20 [TX]	[a] Blooms the Chemist Amlodipine/Atorvastatin 10/20 [IB]
						[a] Cadatin 10/20 [FZ]	[a] Cadivast 10/20 [AF]
						[a] Caduet 10/20 [PF]	[a] Chem mart Amlodipine/Atorvastatin 10/20 [CH]
						[a] Terry White Chemists Amlodipine/Atorvastatin 10/20 [TW]	

amlodipine 10 mg + atorvastatin 40 mg tablet, 30

9055N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.60	18.77	[a] APO-Amlodipine/Atorvastatin 10/40 [TX] [a] Cadatin 10/40 [FZ] [a] Caduet 10/40 [PF] [a] Terry White Chemists Amlodipine/Atorvastatin 10/40 [TW]	[a] Blooms the Chemist Amlodipine/Atorvastatin 10/40 [IB] [a] Cadivast 10/40 [AF] [a] Chem mart Amlodipine/Atorvastatin 10/40 [CH]

amlodipine 10 mg + atorvastatin 80 mg tablet, 30

9056P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.87	21.04	[a] APO-Amlodipine/Atorvastatin 10/80 [TX] [a] Cadatin 10/80 [FZ] [a] Caduet 10/80 [PF] [a] Terry White Chemists Amlodipine/Atorvastatin 10/80 [TW]	[a] Blooms the Chemist Amlodipine/Atorvastatin 10/80 [IB] [a] Cadivast 10/80 [AF] [a] Chem mart Amlodipine/Atorvastatin 10/80 [CH]

amlodipine 5 mg + atorvastatin 10 mg tablet, 30

9049G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.04	15.21	[a] APO-Amlodipine/Atorvastatin 5/10 [TX] [a] Cadatin 5/10 [FZ] [a] Caduet 5/10 [PF] [a] Terry White Chemists Amlodipine/Atorvastatin 5/10 [TW]	[a] Blooms the Chemist Amlodipine/Atorvastatin 5/10 [IB] [a] Cadivast 5/10 [AF] [a] Chem mart Amlodipine/Atorvastatin 5/10 [CH]

amlodipine 5 mg + atorvastatin 20 mg tablet, 30

9050H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.25	16.42	[a] APO-Amlodipine/Atorvastatin 5/20 [TX] [a] Cadatin 5/20 [FZ] [a] Caduet 5/20 [PF] [a] Terry White Chemists Amlodipine/Atorvastatin 5/20 [TW]	[a] Blooms the Chemist Amlodipine/Atorvastatin 5/20 [IB] [a] Cadivast 5/20 [AF] [a] Chem mart Amlodipine/Atorvastatin 5/20 [CH]

amlodipine 5 mg + atorvastatin 40 mg tablet, 30

9051J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.79	17.96	[a] APO-Amlodipine/Atorvastatin 5/40 [TX] [a] Cadatin 5/40 [FZ] [a] Caduet 5/40 [PF] [a] Terry White Chemists Amlodipine/Atorvastatin 5/40 [TW]	[a] Blooms the Chemist Amlodipine/Atorvastatin 5/40 [IB] [a] Cadivast 5/40 [AF] [a] Chem mart Amlodipine/Atorvastatin 5/40 [CH]

amlodipine 5 mg + atorvastatin 80 mg tablet, 30

9052K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.05	20.22	[a] APO-Amlodipine/Atorvastatin 5/80 [TX] [a] Cadatin 5/80 [FZ]	[a] Blooms the Chemist Amlodipine/Atorvastatin 5/80 [IB] [a] Cadivast 5/80 [AF]

[a] Caduet 5/80 [PF]

[a] Chem mart Amlodipine/Atorvastatin 5/80 [CH]

[a] Terry White Chemists Amlodipine/Atorvastatin 5/80 [TW]

DERMATOLOGICALS

ANTIFUNGALS FOR DERMATOLOGICAL USE

ANTIFUNGALS FOR TOPICAL USE

Antibiotics

NYSTATIN

Authority required (STREAMLINED)

2354

Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person

nystatin 100 000 units/g cream, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1698J NP	2	3	..	*20.45	21.62	Mycostatin [FM]

Imidazole and triazole derivatives

KETOCONAZOLE

Authority required (STREAMLINED)

2354

Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person

ketoconazole 1% shampoo, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9025B NP	‡1	1	..	19.66	20.83	Nizoral 1% [JT]

ketoconazole 2% cream, 30 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9024Y NP	‡1	2	..	24.21	25.38	Nizoral 2% Cream [JT]

ketoconazole 2% shampoo, 60 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1574W NP	‡1	1	..	20.25	21.42	Nizoral 2% [JT]

MICONAZOLE

Authority required (STREAMLINED)

2354

Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person

miconazole 2% solution, 30 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9031H NP	‡1	2	..	21.20	22.37	Daktarin Tincture [JT]

miconazole nitrate 2% cream, 30 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9027D NP	‡1	2	..	17.33	18.50	Daktarin [JT]

miconazole nitrate 2% cream, 70 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9028E NP	‡1	1	..	18.99	20.16	Daktarin [JT]

miconazole nitrate 2% powder: dusting, 30 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9029F NP	‡1	2	..	17.97	19.14	Daktarin [JT]

Other antifungals for topical use

TERBINAFINE

Authority required (STREAMLINED)

2354

Treatment of a fungal or a yeast infection in an Aboriginal or a Torres Strait Islander person

Authority required (STREAMLINED)

3243
Treatment of a fungal or a yeast infection in a patient aged up to 18 years inclusive

terbinafine hydrochloride 1% cream, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9160D NP	2	3	..	*37.33	38.30	[a] Lamisil [NC]

ANTIFUNGALS FOR SYSTEMIC USE

Antifungals for systemic use

▪ GRISEOFULVIN

griseofulvin 125 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1460W NP	1	2	..	26.48	27.65	Grisovin [QA]

griseofulvin 500 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2982Y NP	1	2	..	27.42	28.59	Grisovin 500 [QA]

▪ TERBINAFINE

Authority required
Treatment of a dermatophyte infection in an Aboriginal or a Torres Strait Islander person where topical treatment has failed

Authority required
Treatment of a dermatophyte infection in a patient aged up to 18 years inclusive where topical treatment and griseofulvin have failed

terbinafine 250 mg tablet, 42

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2285G NP	1	..	..	34.20	35.37	[a] GenRx Terbinafine [GX]	[a] Lamisil (Novartis Pharmaceuticals Australia Pty Limited) [NV]
						[a] Sebifin 250 [RA]	[a] Tamsil [RW]
						[a] Terbinafine Actavis [ED]	[a] Terbinafine AN [EA]
						[a] Terbinafine-DRLA [RZ]	[a] Terbinafine GH [GQ]
						[a] Terbinafine Sandoz [SZ]	[a] Tinasil [AF]

▪ TERBINAFINE

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

Authority required
Proximal or extensive (greater than 80% nail involvement) onychomycosis due to dermatophyte infection where topical treatment has failed. This infection must be proven by microscopy or culture and confirmed by an Approved Pathology Authority. The date of the pathology report must be provided at the time of application and must not be more than 12 months old

terbinafine 250 mg tablet, 42

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2804N NP	1	1	..	34.20	35.37	[a] GenRx Terbinafine [GX]	[a] Lamisil (Novartis Pharmaceuticals Australia Pty Limited) [NV]
						[a] Sebifin 250 [RA]	[a] Tamsil [RW]
						[a] Terbinafine Actavis [ED]	[a] Terbinafine AN [EA]
						[a] Terbinafine-DRLA [RZ]	[a] Terbinafine GH [GQ]
						[a] Terbinafine Sandoz [SZ]	[a] Tinasil [AF]

▪ ANTIPSORIATICS

ANTIPSORIATICS FOR TOPICAL USE

Tars

▪ COAL TAR PREPARED

coal tar prepared 1% lotion, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8864M NP	‡1	2	..	32.44	33.61	Exorex [GN]

coal tar prepared 2% foam, 100 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10225E NP	‡1	2	..	33.60	34.77	Scytera [RZ]

Other antipsoriatics for topical use

▪ CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE

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

Authority required (STREAMLINED)
5963
Chronic stable plaque type psoriasis vulgaris
Clinical criteria:
The condition must be inadequately controlled with either a vitamin D analogue or potent topical corticosteroid as monotherapy, AND
Patient must require more than 30 grams of product per month.

betamethasone (as dipropionate) 0.05% + calcipotriol 0.005% gel, 60 g

10075G (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	72.35	38.30	Daivobet 50/500 gel [LO]

▪ CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE

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

Restricted benefit
Chronic stable plaque type psoriasis vulgaris
Clinical criteria:
The condition must be inadequately controlled with either a vitamin D analogue or potent topical corticosteroid as monotherapy.

calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% gel, 30 g

5276Q (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	41.39	38.30	Daivobet 50/500 gel [LO]

▪ CALCIPOTRIOL + BETAMETHASONE DIPROPIONATE

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

Restricted benefit
Chronic stable plaque type psoriasis vulgaris in a patient who is not adequately controlled with either calcipotriol or potent topical corticosteroid monotherapy

calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% ointment, 30 g

9494Q (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	41.39	38.30	Daivobet [LO]

ANTIPSORIATICS FOR SYSTEMIC USE

Retinoids for treatment of psoriasis

▪ ACITRETIN

Caution This drug is a potent teratogen - pregnancy should be avoided for at least two years after cessation of therapy.
Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Authority required (STREAMLINED)
5789
Severe intractable psoriasis
Authority required (STREAMLINED)
5727
Severe disorders of keratinisation

acitretin 10 mg capsule, 100

2019G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	144.09	38.30	[a] Acitretin Actavis [GN] [a] Novatin [TX]	[a] Neotigason [UA]

acitretin 25 mg capsule, 100

2020H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	285.47	38.30	[a] Acitretin Actavis [GN]	[a] Neotigason [UA]

[a] Novatin [TX]

ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

CHEMOTHERAPEUTICS FOR TOPICAL USE

Sulfonamides

SULFADIAZINE SILVER

Restricted benefit

Prevention and treatment of infection in partial or full skin thickness loss due to burns

Restricted benefit

Prevention and treatment of infection in partial or full skin thickness loss due to epidermolysis bullosa

Restricted benefit

Stasis ulcers

sulfadiazine silver 1% cream, 50 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9479X NP	‡1	..	..	20.95	22.12	Flamazine [SN]

CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

CORTICOSTEROIDS, PLAIN

Corticosteroids, weak (group I)

HYDROCORTISONE ACETATE

Restricted benefit

Corticosteroid-responsive dermatoses

hydrocortisone acetate 1% cream, 50 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2881P NP	‡1	1	..	12.28	13.45	[a] Cortic-DS 1% [FM]
			[B]2.35	14.63	13.45	[a] Sigmacort [QA]

hydrocortisone acetate 1% ointment, 50 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2882Q NP	‡1	1	..	12.28	13.45	[a] Cortic-DS 1% [FM]
			[B]2.35	14.63	13.45	[a] Sigmacort [QA]

HYDROCORTISONE ACETATE

Restricted benefit

Corticosteroid-responsive dermatoses

hydrocortisone acetate 1% cream, 50 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5113D DP	‡1	..	..	12.28	13.45	[a] Cortic-DS 1% [FM]
			[B]2.35	14.63	13.45	[a] Sigmacort [QA]

hydrocortisone acetate 1% ointment, 50 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5114E DP	‡1	..	..	12.28	13.45	[a] Cortic-DS 1% [FM]
			[B]2.35	14.63	13.45	[a] Sigmacort [QA]

Corticosteroids, moderately potent (group II)

TRIAMCINOLONE

Restricted benefit

Treatment of corticosteroid-responsive dermatoses

triamcinolone acetonide 0.02% cream, 100 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2117K NP	2	..	..	*17.37	18.54	[a] Tricortone [FM]
			[B]3.28	*20.65	18.54	[a] Aristocort 0.02% [QA]

triamcinolone acetonide 0.02% ointment, 100 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2118L NP	2	..	..	*17.37	18.54	[a] Tricortone [FM]
			[B]3.28	*20.65	18.54	[a] Aristocort 0.02% [QA]

Corticosteroids, potent (group III)

▪ BETAMETHASONE DIPROPIONATE

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

Restricted benefit

Corticosteroid-responsive dermatoses

betamethasone (as dipropionate) 0.05% cream, 15 g

1115Q (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	16.26	17.43	[a] Eleuphrat [FR]
		[B]2.45	18.71	17.43	[a] Diprosone [MK]

betamethasone (as dipropionate) 0.05% ointment, 15 g

1119X (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	16.26	17.43	[a] Eleuphrat [FR]
		[B]2.45	18.71	17.43	[a] Diprosone [MK]

▪ BETAMETHASONE VALERATE

Restricted benefit

Corticosteroid-responsive dermatoses

betamethasone (as valerate) 0.02% cream, 100 g

2812B (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*25.91	27.08	[a] Antroquoril [FR]
					[b] Cortival 1/5 [FM]
		[B]2.48	*28.39	27.08	[a] Celestone-M [MK]
		[B]5.98	*31.89	27.08	[b] Betnovate 1/5 [QA]

▪ BETAMETHASONE VALERATE

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

Restricted benefit

Corticosteroid-responsive dermatoses

betamethasone (as valerate) 0.05% cream, 15 g

2813C (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	12.15	13.32	[a] Cortival 1/2 [FM]
		[B]2.56	14.71	13.32	[a] Betnovate 1/2 [QA]

▪ METHYLPREDNISOLONE

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

Restricted benefit

Treatment of corticosteroid-responsive dermatoses

methylprednisolone aceponate 0.1% cream, 15 g

8054X (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	16.99	18.16	Advantan [BN]

methylprednisolone aceponate 0.1% ointment, 15 g

8055Y (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	16.99	18.16	Advantan [BN]

methylprednisolone aceponate 0.1% ointment, 15 g

8128T (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	16.99	18.16	Advantan [BN]

▪ METHYLPREDNISOLONE

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

Restricted benefit

Eczema

methylprednisolone aceponate 0.1% lotion, 20 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8618N NP	‡1	..	..	17.58	18.75	Advantan [BN]

▪ MOMETASONE

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

Restricted benefit

Treatment of corticosteroid-responsive dermatoses

mometasone furoate 0.1% cream, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1913Q NP	‡1	..	..	14.56	15.73	[a] Momasone [QA]	[a] Novasone [AF]
			[B]2.70	17.26	15.73	[a] Elocon [MK]	

mometasone furoate 0.1% lotion, 30 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8043H NP	‡1	..	..	16.95	18.12	[a] Momasone [QA] [a] Zatamil [EO]	[a] Novasone [AF]
			[B]2.70	19.65	18.12	[a] Elocon [MK]	

mometasone furoate 0.1% ointment, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1915T NP	‡1	..	..	14.56	15.73	[a] Novasone [AF]	[a] Zatamil [EO]
			[B]2.70	17.26	15.73	[a] Elocon [MK]	

Corticosteroids, very potent (group IV)

▪ CLOBETASOL

Authority required (STREAMLINED)

5461

Moderate to severe scalp psoriasis

Clinical criteria:

The condition must be inadequately controlled with either a vitamin D analogue or potent topical corticosteroid as monotherapy; OR

The condition must be inadequately controlled with combination use of a vitamin D analogue and potent topical corticosteroid.

Population criteria:

Patient must be aged 18 years or older.

clobetasol propionate 0.05% shampoo, 125 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10080M	‡1	1	..	48.14	38.30	Clobex [GA]

▪ ANTI-ACNE PREPARATIONS

ANTI-ACNE PREPARATIONS FOR TOPICAL USE

Retinoids for topical use in acne

▪ ADAPALENE + BENZOYL PEROXIDE

Restricted benefit

Severe acne vulgaris

Treatment Phase: Acute treatment

Clinical criteria:

The treatment must in combination with an oral antibiotic.

adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8954G	‡1	1	..	35.62	36.79	Epiduo [GA]

▪ ADAPALENE + BENZOYL PEROXIDE

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

Restricted benefit

Severe acne vulgaris

Clinical criteria:

The treatment must be maintenance therapy.

adapalene 0.1% + benzoyl peroxide 2.5% gel, 30 g

8955H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	3	..	35.62	36.79	Epiduo [GA]

ANTI-ACNE PREPARATIONS FOR SYSTEMIC USE

Retinoids for treatment of acne

▪ ISOTRETINOIN

Caution This drug causes birth defects.

This drug has been reported to cause other frequent and potentially serious toxicity.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Authority required (STREAMLINED)

5224

Severe cystic acne

Clinical criteria:

The condition must be unresponsive to other therapy.

isotretinoin 10 mg capsule, 60

2591J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	37.07	38.24	[a] APO-Isotretinoin [TX] [a] Isotretinoin AN [EA] [a] Oratane [AG] [a] Rocta 10 [RW]	[a] Dermatane [ER] [a] Isotretinoin SCP 10 [CR] [a] Roaccutane [RO]

isotretinoin 20 mg capsule, 60

2592K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	51.97	38.30	[a] APO-Isotretinoin [TX] [a] Isotretinoin AN [EA] [a] Oratane [AG] [a] Rocta 20 [RW]	[a] Dermatane [ER] [a] Isotretinoin SCP 20 [CR] [a] Roaccutane [RO]

isotretinoin 40 mg capsule, 30

2549E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	47.92	38.30	[a] Dermatane [ER]	[a] Oratane [AG]

▪ OTHER DERMATOLOGICAL PREPARATIONS

OTHER DERMATOLOGICAL PREPARATIONS

Agents for dermatitis, excluding corticosteroids

▪ PIMECROLIMUS

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

5482

Atopic dermatitis

Clinical criteria:

The condition must be on the patient's face; OR

The condition must be on the patient's eyelid, AND

Patient must have 1 or more of the following contraindications to topical corticosteroids: (i) perioral dermatitis; (ii) periorbital dermatitis; (iii) rosacea; (iv) epidermal atrophy; (v) dermal atrophy; (vi) allergy to topical corticosteroids; (vii) cataracts; (viii) glaucoma; (ix) raised intraocular pressure, AND

Patient must not receive more than two 15 g packs of PBS-subsidised pimecrolimus per 6-month period.

Population criteria:

Patient must be at least 3 months of age.

Authority required (STREAMLINED)

5472

Atopic dermatitis

Treatment Phase: Short-term (up to 3 weeks) intermittent treatment

Clinical criteria:

The condition must be on the patient's face; OR

The condition must be on the patient's eyelid, AND

Patient must have failed to achieve satisfactory disease control with intermittent topical corticosteroid therapy, AND
The condition must have been initially diagnosed more than three months prior to this treatment, AND
Patient must not receive more than two 15 g packs of PBS-subsidised pimecrolimus per 6-month period.
Population criteria:
Patient must be at least 3 months of age.
Failure to achieve satisfactory disease control with intermittent topical corticosteroid therapy is manifest by:
(i) failure of the facial skin to clear despite at least 2 weeks of topical hydrocortisone 1% applied every day; or
(ii) failure of the facial skin to clear despite at least 1 week of a moderate or potent topical corticosteroid applied every day; or
(iii) clearing of the facial skin with at least 2 weeks of topical hydrocortisone 1% applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions; or
(iv) clearing of the facial skin with at least 1 week of a moderate or potent topical corticosteroid applied every day, but almost immediate and significant flare in facial disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions

pimecrolimus 1% cream, 15 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8802G	‡1	1	..	33.03	34.20	Elidel [HM]

Other dermatologicals

▪ DAPSONE

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

dapsone 100 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1272Y NP	1	1	..	103.19	38.30	Link Medical Products Pty Ltd [LM]

dapsone 25 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8801F NP	1	1	..	91.74	38.30	Link Medical Products Pty Ltd [LM]

▪ IMIQUIMOD

Note The patient or carer must be able to understand and administer the imiquimod dosing regimen.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Treatment of recurrent (previously treated) lesions will not be authorised.
Note Pharmaceutical benefits that have the form imiquimod single use sachets and pharmaceutical benefits that have the form imiquimod multi-use pump are equivalent for the purposes of substitution.

Authority required
Superficial basal cell carcinoma
Clinical criteria:
The condition must be previously untreated, AND
The condition must be confirmed by biopsy, AND
Patient must have normal immune function, AND
The condition must not be suitable for treatment with surgical excision; OR
The condition must not be suitable for treatment with cryotherapy; OR
The condition must not be suitable for treatment with curettage with diathermy, AND
Patient must require topical drug therapy.
The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application.

imiquimod 5% cream, 12 x 250 mg sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2546B	1	1	..	99.78	38.30	[a] Aldiq [QA]	[a] APO-Imiquimod [TX]
			[B]2.69	102.47	38.30	[a] Aldara [IA]	

imiquimod 5% cream, 2 x 2 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2637T	1	1	[B]5.38	105.16	38.30	[a] Aldara Pump [IA]

GENITO URINARY SYSTEM AND SEX HORMONES

OTHER GYNECOLOGICALS

CONTRACEPTIVES FOR TOPICAL USE

Intrauterine contraceptives

LEVONORGESTREL

Restricted benefit
Contraception
Restricted benefit
Idiopathic menorrhagia
Clinical criteria:
The treatment must be in a patient where oral treatments are ineffective.
Restricted benefit
Idiopathic menorrhagia
Clinical criteria:
The treatment must be in a patient where oral treatments are contraindicated.

levonorgestrel 52 mg intrauterine drug delivery system, 1 system

8633J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	241.88	38.30	Mirena [BN]

NP

OTHER GYNECOLOGICALS

Prolactine inhibitors

BROMOCRIPTINE

Restricted benefit
Prevention of the onset of lactation
Clinical criteria:
The treatment must occur in the puerperium, AND
The treatment must be for medical reasons.

bromocriptine 2.5 mg tablet, 30

1444B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	21.29	22.46	[a] Kripton 2.5 [AF]	[a] Parlodel [NV]

NP

BROMOCRIPTINE

Caution Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Note For item codes 1443Y and 1559C, pharmaceutical benefits that have the form tablet 2.5 mg (base) are equivalent for the purposes of substitution.

Restricted benefit
Acromegaly
Restricted benefit
Parkinson disease
Restricted benefit
Pathological hyperprolactinaemia
Clinical criteria:
Patient must be one in whom surgery is not indicated.
Restricted benefit
Pathological hyperprolactinaemia
Clinical criteria:
Patient must have had surgery for this condition with incomplete resolution.
Restricted benefit
Pathological hyperprolactinaemia
Clinical criteria:
Patient must be one in whom radiotherapy is not indicated.
Restricted benefit
Pathological hyperprolactinaemia
Clinical criteria:
Patient must have had radiotherapy for this condition with incomplete resolution.

bromocriptine 2.5 mg tablet, 30

1443Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*32.17	33.34	[a] Parlodel [NV]

bromocriptine 2.5 mg tablet, 60

1559C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	32.16	33.33	[a] Kripton 2.5 [AF]

▪ CABERGOLINE

Restricted benefit
Prevention of the onset of lactation
Clinical criteria:
The treatment must occur in the puerperium, AND
The treatment must be for medical reasons.

cabergoline 500 microgram tablet, 2

8115D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	23.78	24.95	[a] APO-Cabergoline [TX]	[a] Dostinex [PF]

▪ CABERGOLINE

Restricted benefit
Pathological hyperprolactinaemia
Clinical criteria:
Patient must be one in whom surgery is not indicated.
Restricted benefit
Pathological hyperprolactinaemia
Clinical criteria:
Patient must have had surgery for this condition with incomplete resolution.
Restricted benefit
Pathological hyperprolactinaemia
Clinical criteria:
Patient must be one in whom radiotherapy is not indicated.
Restricted benefit
Pathological hyperprolactinaemia
Clinical criteria:
Patient must have had radiotherapy for this condition with incomplete resolution.

cabergoline 500 microgram tablet, 8

8114C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	63.88	38.30	[a] APO-Cabergoline [TX]	[a] Dostinex [PF]

▪ QUINAGOLIDE

Restricted benefit
Pathological hyperprolactinaemia
Clinical criteria:
Patient must be one in whom surgery is not indicated.
Restricted benefit
Pathological hyperprolactinaemia
Clinical criteria:
Patient must have had surgery for this condition with incomplete resolution.
Restricted benefit
Pathological hyperprolactinaemia
Clinical criteria:
Patient must be one in whom radiotherapy is not indicated.
Restricted benefit
Pathological hyperprolactinaemia
Clinical criteria:
Patient must have had radiotherapy for this condition with incomplete resolution.

quinagolide 25 microgram tablet [3 tablets] (&) quinagolide 50 microgram tablet [3 tablets], 6

8860H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	14.59	15.76	Norprolac [FP]

quinagolide 75 microgram tablet, 30

8822H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	52.09	38.30	Norprolac [FP]

SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE

Progestogens and estrogens, fixed combinations

ETHINYLOESTRADIOL + LEVONORGESTREL

ethinyloestradiol 30 microgram + levonorgestrel 150 microgram tablet [84] (&) inert substance tablet [28], 112 tablets [4 x 28]

1394J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	18.14	19.31	[a] Monofeme 28 [FZ]	
						[b] Eleanor 150/30 ED [EA]	[b] Evelyn 150/30 ED [GQ]
						[b] Femme-Tab ED 30/150 [AE]	[b] Lenest 30 ED [AF]
						[b] Levlen ED [SY]	[b] Micronelle 30 ED [TX]
			[B]11.41	29.55	19.31	[b] Microgynon 30 ED [BN]	
			[B]12.50	30.64	19.31	[a] Nordette 28 [PF]	

ethinyloestradiol 50 microgram + levonorgestrel 125 microgram tablet [84] (&) inert substance tablet [28], 112 tablets [4 x 28]

1456P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	18.14	19.31	Microgynon 50 ED [BN]

ethinyloestradiol 20 microgram + levonorgestrel 100 microgram tablet [84] (&) inert substance tablet [28], 112 [4 x 28]

2416E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	18.14	19.31	Femme-Tab ED 20/100 [AE]

ETHINYLOESTRADIOL + NORETHISTERONE

ethinyloestradiol 35 microgram + norethisterone 1 mg tablet [84] (&) inert substance tablet [28], 112 tablets [4 x 28]

2775C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	19.15	20.32	[a] Norimin-1 28 Day [FZ]
			[B]9.28	28.43	20.32	[a] Brevinor-1 [PF]

ethinyloestradiol 35 microgram + norethisterone 500 microgram tablet [84] (&) inert substance tablet [28], 112 tablets [4 x 28]

2774B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	19.15	20.32	[a] Norimin 28 Day [FZ]
			[B]9.28	28.43	20.32	[a] Brevinor [PF]

MESTRANOL + NORETHISTERONE

mestranol 50 microgram + norethisterone 1 mg tablet [84] (&) inert substance tablet [28], 112 tablets [4 x 28]

3179H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	19.15	20.32	Norinyl-1/28 [PF]

Progestogens and estrogens, sequential preparations

ETHINYLOESTRADIOL + LEVONORGESTREL

ethinyloestradiol 30 microgram + levonorgestrel 50 microgram tablet [24] (&) ethinyloestradiol 40 microgram + levonorgestrel 75 microgram tablet [20] (&) ethinyloestradiol 30 microgram + levonorgestrel 125 microgram tablet [40] (&) inert substance tablet [28], 112 [4 x 28]

1392G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	18.14	19.31	[a] Trifeme 28 [FZ]
						[b] Logynon ED [SY]
			[B]11.41	29.55	19.31	[b] Triquilar ED [BN]
			[B]12.50	30.64	19.31	[a] Triphasil 28 [PF]

Progestogens

ETONOGESTREL

etonogestrel 68 mg implant, 1

8487Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP MW	1	..	..	192.41	38.30	Implanon NXT [MK]

▪ LEVONORGESTREL

levonorgestrel 30 microgram tablet, 112 tablets [4 x 28]

2913H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP MW	1	2	..	19.43	20.60	Microlut 28 [BN]

▪ MEDROXYPROGESTERONE

medroxyprogesterone acetate 150 mg/mL injection, 1 mL vial

3118D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	1	..	24.55	25.72	[a] Depo-Ralovera [FZ]
			[B]5.38	29.93	25.72	[a] Depo-Provera [PF]

▪ NORETHISTERONE

norethisterone 350 microgram tablet, 112 tablets [4 x 28]

1967M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	19.15	20.32	Noriday 28 Day [PF]

ANDROGENS

3-oxoandrosten (4) derivatives

▪ TESTOSTERONE

Authority required

Androgen deficiency

Clinical criteria:

Patient must have an established pituitary or testicular disorder.

Treatment criteria:

Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Androgen deficiency

Clinical criteria:

Patient must not have an established pituitary or testicular disorder, AND

The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

Population criteria:

Patient must be aged 40 years or older.

Treatment criteria:

Must be treated by a specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

Authority required

Micropenis

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Pubertal induction

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Constitutional delay of growth or puberty

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

testosterone 1% (12.5 mg/actuation) gel, 2 x 60 actuations

10380H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	4	..	87.03	38.30	Testogel [HB]

testosterone 1% (50 mg/5 g) gel, 30 x 5 g sachets

8830R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	5	..	87.03	38.30	Testogel [HB]

testosterone 2% (30 mg/1.5 mL actuation) transdermal solution, 60 actuations

2341F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	5	..	76.09	38.30	Axiron [LY]

testosterone 2.5 mg/24 hours patch, 60

8460G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	5	..	87.64	38.30	Androderm [AG]

testosterone 5 mg/24 hours patch, 30

8619P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	5	..	87.64	38.30	Androderm [AG]

testosterone 50 mg/mL cream, 50 mL

10378F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	6	..	73.28	38.30	AndroForte 5 [LX]

▪ TESTOSTERONE ENANTHATE

Authority required

Androgen deficiency

Clinical criteria:

Patient must have an established pituitary or testicular disorder.

Treatment criteria:

Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Androgen deficiency

Clinical criteria:

Patient must not have an established pituitary or testicular disorder, AND

The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

Population criteria:

Patient must be aged 40 years or older.

Treatment criteria:

Must be treated by a specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

Authority required

Micropenis

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Pubertal induction

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Constitutional delay of growth or puberty

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

testosterone enanthate 250 mg/mL injection, 3 x 1 mL syringes

2114G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	32.77	33.94	Primoteston Depot [BN]

▪ TESTOSTERONE UNDECANOATE

Authority required

Androgen deficiency

Clinical criteria:

Patient must have an established pituitary or testicular disorder.

Treatment criteria:

Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Androgen deficiency

Clinical criteria:

Patient must not have an established pituitary or testicular disorder, AND

The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

Population criteria:

Patient must be aged 40 years or older.

Treatment criteria:

Must be treated by a specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

Authority required

Micropenis

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Pubertal induction

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

Authority required

Constitutional delay of growth or puberty

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

The name of the specialist must be included in the authority application.

testosterone undecanoate 1 g/4 mL injection, 4 mL vial

10205D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	132.19	38.30	Reandron 1000 [BN]

testosterone undecanoate 40 mg capsule, 60

2115H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	36.12	37.29	Andriol Testocaps [MK]

ESTROGENS

Natural and semisynthetic estrogens, plain

▪ OESTRADIOL

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

oestradiol 10 microgram pessary: modified release, 18

10203B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	31.67	32.84	Vagifem Low [NO]

oestradiol 2 mg tablet, 56

8274L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	16.62	17.79	Zumenon [GO]

oestradiol valerate 1 mg tablet, 56

1663M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	14.99	16.16	Progynova [BN]

oestradiol valerate 2 mg tablet, 56

1664N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	16.92	18.09	Progynova [BN]

▪ OESTRADIOL

Note Oestradiol should be used in conjunction with an oral progestogen in women with an intact uterus.

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

oestradiol 0.1% (1 mg/g) gel, 28 x 1 g sachets

8286D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	19.70	20.87	Sandrena [AS]

oestradiol 100 microgram/24 hours patch, 4

8126Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	21.47	22.64	Climara 100 [BN]

oestradiol 100 microgram/24 hours patch, 8

8312L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	21.47	22.64	Estraderm MX 100 [JU]

oestradiol 100 microgram/24 hours patch, 8

8765H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	21.47	22.64	Estradot 100 [NV]

oestradiol 25 microgram/24 hours patch, 4

8485N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	19.70	20.87	Climara 25 [BN]

oestradiol 25 microgram/24 hours patch, 8

8311K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	19.70	20.87	Estraderm MX 25 [JU]

oestradiol 25 microgram/24 hours patch, 8

8761D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	19.70	20.87	Estradot 25 [NV]

oestradiol 37.5 microgram/24 hours patch, 8

8762E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	19.70	20.87	Estradot 37.5 [NV]

oestradiol 50 microgram/24 hours patch, 4

8125P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	19.70	20.87	Climara 50 [BN]

oestradiol 50 microgram/24 hours patch, 8

8140K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	19.70	20.87	Estraderm MX 50 [JU]

oestradiol 50 microgram/24 hours patch, 8

8763F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	19.70	20.87	Estradot 50 [NV]

oestradiol 75 microgram/24 hours patch, 4

8486P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	21.47	22.64	Climara 75 [BN]

oestradiol 75 microgram/24 hours patch, 8

8764G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	21.47	22.64	Estradot 75 [NV]

▪ OESTRIOL

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

oestriol 0.1% (1 mg/g) cream, 15 g

1781R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	1	..	20.89	22.06	Ovestin [AS]

oestriol 500 microgram pessary, 15

1771F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	2	..	22.68	23.85	Ovestin Ovula [AS]

PROGESTOGENS

Pregnen (4) derivatives

▪ MEDROXYPROGESTERONE

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

medroxyprogesterone acetate 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2321E NP	1	2	..	17.29	18.46	[a] Ralovera [FZ]
			[B]5.59	22.88	18.46	[a] Provera [PF]

medroxyprogesterone acetate 5 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2323G NP	1	2	..	18.42	19.59	[a] Ralovera [FZ]
			[B]5.59	24.01	19.59	[a] Provera [PF]

▪ MEDROXYPROGESTERONE

Restricted benefit
Endometriosis

medroxyprogesterone acetate 10 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2722G	1	2	..	33.32	34.49	[a] Ralovera [FZ]
			[B]5.60	38.92	34.49	[a] Provera [PF]

Estren derivatives

▪ NORETHISTERONE

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

norethisterone 5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2993M NP	1	2	..	32.63	33.80	Primolut N [BN]

PROGESTOGENS AND ESTROGENS IN COMBINATION

Progestogens and estrogens, fixed combinations

▪ OESTRADIOL + DYDROGESTERONE

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

oestradiol 1 mg + dydrogesterone 5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10142T NP	1	5	..	21.15	22.32	Femoston-Conti [GO]

▪ OESTRADIOL + NORETHISTERONE ACETATE

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

oestradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch, 8

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8427M NP	‡1	5	..	21.47	22.64	Estalis continuous 50/140 [NV]

oestradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch, 8

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8428N NP	‡1	5	..	21.47	22.64	Estalis continuous 50/250 [NV]

Progestogens and estrogens, sequential preparations

▪ NORETHISTERONE ACETATE + OESTRADIOL (&) OESTRADIOL

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

oestradiol 50 microgram/24 hours patch [4] (&) oestradiol 50 microgram/24 hours + norethisterone acetate 140 microgram/24 hours patch [4], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8425K NP	‡1	5	..	21.47	22.64	Estalis sequi 50/140 [NV]

oestradiol 50 microgram/24 hours patch [4] (&) oestradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch [4], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8426L NP	‡1	5	..	21.47	22.64	Estalis sequi 50/250 [NV]

▪ OESTRADIOL (&) OESTRADIOL + DYDROGESTERONE

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

oestradiol 1 mg tablet [14] (&) oestradiol 1 mg + dydrogesterone 10 mg tablet [14], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10146B NP	‡1	5	..	21.15	22.32	Femoston 1/10 [GO]

oestradiol 2 mg tablet [14] (&) oestradiol 2 mg + dydrogesterone 10 mg tablet [14], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8244X NP	‡1	5	..	21.15	22.32	Femoston 2/10 [GO]

GONADOTROPINS AND OTHER OVULATION STIMULANTS

Gonadotropins

▪ FOLLITROPIN ALFA

Note Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomiphene citrate and/or gonadorelin and failed to have conceived.
Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.
Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.
Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

Restricted benefit
Anovulatory infertility
Restricted benefit
For the treatment of infertility in males due to hypogonadotrophic hypogonadism, following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis. Combined treatment with HCG must be given

follitropin alfa 300 units (21.84 microgram)/0.5 mL injection, 0.5 mL cartridge

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8713N	3	5	..	*464.61	38.30	Gonal-f Pen [SG]

follitropin alfa 450 units (32.76 microgram)/0.75 mL injection, 0.75 mL cartridge

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8714P	3	5	..	*694.89	38.30	Gonal-f Pen [SG]

follitropin alfa 900 units (65.52 microgram)/1.5 mL injection, 1.5 mL cartridge

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8715Q	2	5	..	*925.15	38.30	Gonal-f Pen [SG]

▪ FOLLITROPIN BETA

Note Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomiphene citrate and/or gonadorelin and failed to have conceived.
Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.
Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.
Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

Restricted benefit
Anovulatory infertility
Restricted benefit

For the treatment of infertility in males due to hypogonadotrophic hypogonadism, following failure of 6 months' treatment with human chorionic gonadotrophin to achieve adequate spermatogenesis. Combined treatment with HCG must be given

follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8565T	3	5	..	*479.88	38.30	Puregon 300 IU/0.36 mL [MK]

follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8566W	2	5	..	*623.03	38.30	Puregon 600 IU/0.72 mL [MK]

follitropin beta 900 units/1.08 mL injection, 1.08 mL cartridge

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8871X	2	5	..	*924.19	38.30	Puregon 900 IU/1.08 mL [MK]

▪ GONADOTROPHIN CHORIONIC HUMAN

Note Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomiphene citrate and/or gonadorelin and failed to have conceived.
Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.
Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.
Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.

Restricted benefit
Anovulatory infertility

Restricted benefit
For the treatment of infertility in males due to hypogonadotrophic hypogonadism

Restricted benefit
For the treatment of infertility in males associated with isolated luteinising hormone deficiency

Restricted benefit
For the treatment of males who have combined deficiency of human growth hormone and gonadotrophins and in whom the absence of secondary sexual characteristics indicates a lag in maturation

Restricted benefit
For the treatment of boys over the age of 16 years who show clinical evidence of hypogonadism or delayed puberty. Treatment must not extend beyond 6 months

gonadotrophin chorionic human 1500 units injection [3 ampoules] (&) inert substance diluent [3 x 1 mL ampoules], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1581F	1	5	..	50.84	38.30	Pregnyl [MK]

Ovulation stimulants, synthetic

▪ CLOMIPHENE

Note Care must be taken to comply with the provisions of State/Territory law when prescribing clomiphene citrate.

Restricted benefit
Anovulatory infertility

Restricted benefit
Patients undergoing in-vitro fertilisation

clomiphene citrate 50 mg tablet, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1211R	1	5	..	34.85	36.02	[a] Clomid [SW]	[a] Serophene [SG]

ANTIANDROGENS

Antiandrogens, plain

▪ CYPROTERONE

cyproterone acetate 100 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8019C	1	5	..	81.65	38.30	[a] Cyprocur 100 [QA] [a] Cyproterone AN [EA] [a] GenRx Cyproterone Acetate [GX]	[a] Cyprostat-100 [SY] [a] Cyproterone Sandoz [HX] [a] Procur 100 [ED]
			[B]1.80	83.45	38.30	[a] Androcur-100 [BN]	

cyproterone acetate 50 mg tablet, 50

1270W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*101.89	38.30	[a] Cyprocur 50 [QA] [a] Cyprostat [SY] [a] Cyproterone Sandoz [HX] [a] GenRx Cyproterone Acetate [GX]	[a] Cyprone [AF] [a] Cyproterone AN [EA] [a] Cyrotone [ER] [a] Procur [ED]
			[B]2.88	*104.77	38.30	[a] Androcur [BN]	

▪ CYPROTERONE

Caution This drug should not be used during pregnancy as it may result in feminisation of the male foetus.

Authority required (STREAMLINED)

5532

Moderate to severe androgenisation

Clinical criteria:

The condition must not be indicated by acne alone, as this is not a sufficient indication of androgenisation, AND

Patient must not be pregnant.

Population criteria:

Patient must be female.

cyproterone acetate 50 mg tablet, 20

1269T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	28.71	29.88	[a] Cyprocur 50 [QA] [a] Cyprostat [SY] [a] Cyproterone Sandoz [HX] [a] Procur [ED]	[a] Cyprone [AF] [a] Cyproterone AN [EA] [a] GenRx Cyproterone Acetate [GX]
			[B]3.05	31.76	29.88	[a] Androcur [BN]	

OTHER SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

Antigonadotropins and similar agents

▪ DANAZOL

Caution Pregnancy must be excluded prior to administration of this drug.

Authority required (STREAMLINED)

1090

Endometriosis, visually proven

Authority required (STREAMLINED)

1151

Hereditary angio-oedema

Authority required (STREAMLINED)

2639

Short-term treatment (up to 6 months) of intractable primary menorrhagia (Treatment of this indication is limited to 6 months. See Australian Product Information)

Authority required (STREAMLINED)

2640

Short-term treatment (up to 6 months) of severe benign (fibrocystic) breast disease or mastalgia associated with severe symptomatic benign breast disease in patients refractory to other treatments (Treatment of this indication is limited to 6 months. See Australian Product Information)

danazol 100 mg capsule, 100

1285P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	55.47	38.30	Azol 100 [AF]

danazol 200 mg capsule, 100

1287R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	79.99	38.30	Azol 200 [AF]

▪ GESTRINONE

Authority required (STREAMLINED)

3652

Short-term treatment (up to 6 months) of visually proven endometriosis (only 1 course of not more than 6 months' therapy may be prescribed)

gestrinone 2.5 mg capsule, 8

8015W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	75.53	38.30	Dimetriose [SW]

Progesterone receptor modulators

▪ MIFEPRISTONE (&) MISOPROSTOL

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required
Termination of an intra-uterine pregnancy
Clinical criteria:
The condition must be an intra-uterine pregnancy of up to 63 days of gestation.
Treatment criteria:
Must be treated by a prescriber who is registered with the MS 2 Step Prescribing Program.

mifepristone 200 mg tablet [1] (&) misoprostol 200 microgram tablet [4], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10211K	‡1	..	..	311.12	38.30	MS-2 Step [XH]

▪ UROLOGICALS

UROLOGICALS

Drugs for urinary frequency and incontinence

▪ OXYBUTYNIN

Restricted benefit
Detrusor overactivity

oxybutynin hydrochloride 5 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8039D NP	1	5	..	16.54	17.71	[a] Ditropan [SW] [a] Oxybutynin Winthrop [WA]	[a] Oxybutynin Sandoz [SZ]

▪ OXYBUTYNIN

Restricted benefit
Detrusor overactivity in a patient who cannot tolerate oral oxybutynin, or who cannot swallow oral oxybutynin

oxybutynin 3.9 mg/24 hours patch, 8

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9454N NP	‡1	5	..	35.47	36.64	Oxytrol [AG]

▪ PROPANTHELINE

Restricted benefit
Detrusor overactivity

propantheline bromide 15 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1953T NP	2	5	..	*26.99	28.16	Pro-Banthine [RW]

Other urologicals

▪ BICARBONATE

sodium bicarbonate 840 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9470K NP	1	2	..	16.68	17.85	Sodibic [AS]

▪ PHENOXYBENZAMINE

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

Restricted benefit
Phaeochromocytoma
Restricted benefit
Neurogenic urinary retention

phenoxybenzamine hydrochloride 10 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1862B NP	1	5	..	1102.60	38.30	Dibenyline [GH]

phenoxybenzamine hydrochloride 10 mg capsule, 100

9286R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	1102.60	38.30	Dibenzyline [BZ]

phenoxybenzamine hydrochloride 10 mg capsule, 30

1166J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	3	5	..	*997.08	38.30	Amdipharm Mercury (Australia) Pty Limited [GH]

DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY

Alpha-adrenoreceptor antagonists

▪ DUTASTERIDE + TAMSULOSIN

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

Authority required (STREAMLINED)
6189
Benign prostatic hyperplasia
Clinical criteria:
Patient must have lower urinary tract symptoms, AND
Patient must have moderate to severe benign prostatic hyperplasia.

dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram capsule: modified release, 30

5490Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	34.47	35.64	Duodart 500ug/400ug [GK]

Testosterone-5-alpha reductase inhibitors

▪ DUTASTERIDE

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

Authority required (STREAMLINED)
6202
Benign prostatic hyperplasia
Clinical criteria:
Patient must have lower urinary tract symptoms, AND
Patient must have moderate to severe benign prostatic hyperplasia, AND
The treatment must be in combination with an alpha-antagonist.

dutasteride 500 microgram capsule, 30

5468T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	30.26	31.43	Avodart [GK]

▪ SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

▪ PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES

ACTH

▪ TETRACOSACTRIN

tetracosactrin 1 mg/mL injection: modified release, 1 mL ampoule

2832C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	5	5	..	*66.43	38.30	Synacthen Depot 1 mg/1 mL [LM]

Thyrotropin

▪ THYROTROPIN ALFA

Restricted benefit
Ablation of thyroid remnant tissue
Clinical criteria:
Patient must have undergone a thyroidectomy, AND
The treatment must be in combination with radioactive iodine, AND
Patient must not have a known metastatic disease.

thyrotropin alfa 900 microgram injection, 2 vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2700D	1	..	..	1802.17	38.30	Thyrogen [GZ]

POSTERIOR PITUITARY LOBE HORMONES

Vasopressin and analogues

▪ DESMOPRESSIN

Authority required (STREAMLINED)

5266

Cranial diabetes insipidus

desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8711L	2	5	..	*143.95	38.30	Minirin Nasal Spray [FP]

desmopressin acetate 100 microgram/mL nasal drops, 2.5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2129C	5	5	..	*144.08	38.30	Minirin [FP]

desmopressin acetate 200 microgram tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8662X	3	5	..	*160.23	38.30	Minirin [FP]

▪ DESMOPRESSIN

Note Not to be used in preference to enuresis alarms.

Note Only one application per six months with no more than twice the maximum quantity will be authorised for the tablets.

Authority required (STREAMLINED)

5413

Primary nocturnal enuresis

Clinical criteria:

Patient must be refractory to an enuresis alarm.

Population criteria:

Patient must be 6 years of age or older.

Authority required (STREAMLINED)

5295

Primary nocturnal enuresis

Clinical criteria:

Patient must be one in whom an enuresis alarm is contraindicated.

Population criteria:

Patient must be 6 years of age or older.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

desmopressin acetate 200 microgram tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8663Y (NP)	1	5	..	60.36	38.30	Minirin [FP]

▪ DESMOPRESSIN

Caution Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.

Note Not to be used in preference to enuresis alarms.

Authority required (STREAMLINED)

5342

Primary nocturnal enuresis

Clinical criteria:

Patient must be refractory to an enuresis alarm.

Population criteria:

Patient must be 6 years of age or older.

Authority required (STREAMLINED)

5267

Primary nocturnal enuresis

Clinical criteria:

Patient must be one in whom an enuresis alarm is contraindicated.

Population criteria:

Patient must be 6 years of age or older.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8712M NP	‡1	5	..	77.18	38.30	Minirin Nasal Spray [FP]

▪ DESMOPRESSIN

Note Not to be used in preference to enuresis alarms.

Note Only one application per six months will be authorised for the wafers. No more than twice the maximum quantity for the 120 micrograms wafers and no applications for increased maximum quantities for the 240 micrograms wafers will be authorised.

Authority required (STREAMLINED)

5412

Primary nocturnal enuresis

Clinical criteria:

Patient must be refractory to an enuresis alarm.

Population criteria:

Patient must be 6 years of age or older.

Authority required (STREAMLINED)

5226

Primary nocturnal enuresis

Clinical criteria:

Patient must be one in whom an enuresis alarm is contraindicated.

Population criteria:

Patient must be 6 years of age or older.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

desmopressin 120 microgram wafer: sublingual, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9398P NP	1	5	..	66.06	38.30	Minirin Melt [FP]

desmopressin 240 microgram wafer: sublingual, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8975J NP	1	5	..	105.01	38.30	Minirin Melt [FP]

HYPOTHALAMIC HORMONES

Gonadotropin-releasing hormones

▪ NAFARELIN

Authority required

Endometriosis

Treatment Phase: Intial treatment, for up to 6 months

Clinical criteria:

The condition must be visually proven.

Authority required

Endometriosis

Treatment Phase: Subsequent treatment, for up to 6 months

Clinical criteria:

The condition must be visually proven, AND

The treatment must not be within 2 years of the end of the previous course of treatment with this drug, AND

Patient must have had a recent bone density assessment.

The date of the bone density assessment must be provided.

nafarelin 200 microgram/actuation nasal spray, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2962X	‡1	5	..	118.69	38.30	Synarel [PF]

▪ CORTICOSTEROIDS FOR SYSTEMIC USE

CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN

Mineralocorticoids

▪ FLUDROCORTISONE ACETATE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

fludrocortisone acetate 100 microgram tablet, 100

1433K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	1	..	*44.23	38.30	Florinef [QA]

Glucocorticoids

▪ BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE

Restricted benefit
For local intra-articular or peri-articular infiltration
Restricted benefit
Keloid
Restricted benefit
Lichen planus hypertrophic

betamethasone (as sodium phosphate) 2.96 mg/mL + betamethasone (as acetate) 2.71 mg/mL injection, 5 x 1 mL ampoules

5034Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	26.58	27.75	Celestone Chronodose [MK]

▪ BETAMETHASONE ACETATE + BETAMETHASONE SODIUM PHOSPHATE

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

Restricted benefit
Alopecia areata
Restricted benefit
For local intra-articular or peri-articular infiltration
Restricted benefit
Granulomata, dermal
Restricted benefit
Keloid
Restricted benefit
Lichen planus hypertrophic
Restricted benefit
Lichen simplex chronicus
Restricted benefit
Lupus erythematosus, chronic discoid
Restricted benefit
Necrobiosis lipoidica
Restricted benefit
Uveitis

betamethasone (as sodium phosphate) 2.96 mg/mL + betamethasone (as acetate) 2.71 mg/mL injection, 5 x 1 mL ampoules

2694T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	26.58	27.75	Celestone Chronodose [MK]

▪ CORTISONE

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

cortisone acetate 25 mg tablet, 60

1247P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	4	..	19.76	20.93	Cortate [AS]

cortisone acetate 5 mg tablet, 50

1246N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	4	..	17.75	18.92	Cortate [AS]

▪ DEXAMETHASONE

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

DEXAMETHASONE Tablet 4 mg, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2507Y NP	1	4	..	15.62	16.79	Dexmethsone [AS]

DEXAMETHASONE Tablet 500 micrograms, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1292B NP	1	4	..	12.52	13.69	Dexmethsone [AS]

▪ DEXAMETHASONE SODIUM PHOSPHATE

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

DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 4 mg dexamethasone phosphate in 1 mL, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2509C NP	1	..	..	15.69	16.86	[a] Dexamethasone Mylan [AF]	[a] Hospira Pty Limited [HH]

DEXAMETHASONE SODIUM PHOSPHATE Injection equivalent to 8 mg dexamethasone phosphate in 2 mL, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1291Y NP	1	1	..	20.00	21.17	[a] Dexamethasone Mylan [AF]	[a] Hospira Pty Limited [HH]

▪ HYDROCORTISONE

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

hydrocortisone 20 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1500Y NP	1	4	..	31.06	32.23	Hysone 20 [AF]

hydrocortisone 4 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1499X NP	1	4	..	24.88	26.05	Hysone 4 [AF]

▪ HYDROCORTISONE SODIUM SUCCINATE

hydrocortisone (as sodium succinate) 100 mg injection [1 vial] (&) inert substance diluent [2 mL vial], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1501B NP	2	..	..	*20.23	21.40	Solu-Cortef [PF]

hydrocortisone (as sodium succinate) 250 mg injection [1 vial] (&) inert substance diluent [2 mL vial], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3096Y NP	1	..	..	19.18	20.35	Solu-Cortef [PF]

▪ HYDROCORTISONE SODIUM SUCCINATE

Restricted benefit
For use in a hospital

hydrocortisone (as sodium succinate) 100 mg injection [1 vial] (&) inert substance diluent [2 mL vial], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1510L NP	6	..	..	*39.81	38.30	Solu-Cortef [PF]

hydrocortisone (as sodium succinate) 100 mg injection [1 vial] (&) inert substance diluent [2 mL vial], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5118J DP	6	..	..	*39.81	38.30	Solu-Cortef [PF]

hydrocortisone (as sodium succinate) 250 mg injection [1 vial] (&) inert substance diluent [2 mL vial], 1 pack

1511M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	6	..	..	*62.97	38.30	Solu-Cortef [PF]

hydrocortisone (as sodium succinate) 250 mg injection [1 vial] (&) inert substance diluent [2 mL vial], 1 pack

5119K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	6	..	..	*62.97	38.30	Solu-Cortef [PF]

▪ METHYLPREDNISOLONE

methylprednisolone Powder for injection 1 g (as sodium succinate), 1

5264C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	47.75	38.30	[a] Methylpred [AL]	[a] Methylprednisolone Alphapharm [AF]
						[a] Solu-Medrol [PF]	

▪ METHYLPREDNISOLONE

Restricted benefit

For local intra-articular or peri-articular infiltration

methylprednisolone acetate 40 mg/mL injection, 5 x 1 mL vials

1928L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	23.48	24.65	[a] Depo-Nisolone [FZ]
			[B]2.51	25.99	24.65	[a] Depo-Medrol [PF]

methylprednisolone acetate 40 mg/mL injection, 5 x 1 mL vials

5148Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	23.48	24.65	[a] Depo-Nisolone [FZ]
			[B]2.51	25.99	24.65	[a] Depo-Medrol [PF]

▪ METHYLPREDNISOLONE

Note Pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) and pharmaceutical benefits that have the form methylprednisolone powder for injection 40 mg (as sodium succinate) with diluent are equivalent for the purposes of substitution.

methylprednisolone 40 mg injection [5 vials] (&) inert substance diluent [5 x 1 mL vials], 1 pack

2981X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	24.37	25.54	[a] Solu-Medrol [PF]

methylprednisolone Powder for injection 40 mg (as sodium succinate), 5

5263B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	24.37	25.54	[a] Methylpred [AL]

▪ PREDNISOLONE

prednisolone 1 mg tablet, 100

3152X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	4	..	12.08	13.25	[a] Predsolone [LN]
			[B]0.71	12.79	13.25	[a] Panafcortelone [AS]

prednisolone 25 mg tablet, 30

1916W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	4	..	13.65	14.82	Panafcortelone [AS]	Solone [IA]

prednisolone 5 mg tablet, 60

1917X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	4	..	12.20	13.37	Panafcortelone [AS]	Solone [IA]

▪ PREDNISOLONE SODIUM PHOSPHATE

prednisolone (as sodium phosphate) 5 mg/mL oral liquid, 30 mL

8285C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	17.62	18.79	[a] PredMix [LN]
			[B]2.35	19.97	18.79	[a] Redipred [AS]

▪ PREDNISONE

prednisone 1 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1934T NP	1	4	..	12.54	13.71	[a] Predsone [LN]
			[B]0.79	13.33	13.71	[a] Panafcort [AS]

prednisone 25 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1936X NP	1	4	..	14.76	15.93	Panafcort [AS]	Sone [IA]

prednisone 5 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1935W NP	1	4	..	12.82	13.99	Panafcort [AS]	Sone [IA]

▪ TRIAMCINOLONE

Restricted benefit
For local intra-articular or peri-articular infiltration
Restricted benefit
Keloid
Restricted benefit
Lichen planus hypertrophic

triamcinolone acetonide 10 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5233K DP	1	..	..	26.58	27.75	Kenacort-A10 [QA]

▪ TRIAMCINOLONE

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

Restricted benefit
Alopecia areata
Restricted benefit
For local intra-articular or peri-articular infiltration
Restricted benefit
Granulomata, dermal
Restricted benefit
Keloid
Restricted benefit
Lichen planus hypertrophic
Restricted benefit
Lichen simplex chronicus
Restricted benefit
Lupus erythematosus, chronic discoid
Restricted benefit
Necrobiosis lipoidica
Restricted benefit
Psoriasis

triamcinolone acetonide 10 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2990J NP	1	..	..	26.58	27.75	Kenacort-A10 [QA]

▪ THYROID THERAPY

THYROID PREPARATIONS

Thyroid hormones

▪ LIOTHYRONINE

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

Authority required (STREAMLINED)
1219

Management of patients with thyroid cancer
Authority required (STREAMLINED)
1858
Replacement therapy for hypothyroid patients who have documented intolerance to thyroxine sodium
Authority required (STREAMLINED)
1859
Replacement therapy for hypothyroid patients who have documented resistance to thyroxine sodium
Authority required (STREAMLINED)
1182
Initiation of thyroid therapy in severely hypothyroid patients

liothyronine sodium 20 microgram tablet, 100

2318B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	77.02	38.30	Tertroxin [QA]

▪ THYROXINE

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

thyroxine sodium 100 microgram tablet, 200

2175L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	1	..	25.69	26.86	[a] Eutroxsig [FM]
			[B]1.92	27.61	26.86	[a] Oroxine [QA]

thyroxine sodium 200 microgram tablet, 200

2173J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	1	..	28.32	29.49	[a] Eutroxsig [FM]
			[B]1.93	30.25	29.49	[a] Oroxine [QA]

thyroxine sodium 50 microgram tablet, 200

2174K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	1	..	25.16	26.33	[a] Eutroxsig [FM]
			[B]1.91	27.07	26.33	[a] Oroxine [QA]

thyroxine sodium 75 microgram tablet, 200

9287T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	1	..	25.72	26.89	[a] Eutroxsig [FM]
			[B]1.98	27.70	26.89	[a] Oroxine [QA]

ANTITHYROID PREPARATIONS

Thiouracils

▪ PROPYLTHIOURACIL

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

propylthiouracil 50 mg tablet, 100

1955X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	2	..	*47.23	38.30	PTU [PL]

Sulfur-containing imidazole derivatives

▪ CARBIMAZOLE

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

carbimazole 5 mg tablet, 100

1153Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*30.75	31.92	Carbimazol ARISTO [PQ]	Neo-Mercazole [ZC]

PANCREATIC HORMONES

GLYCOGENOLYTIC HORMONES

Glycogenolytic hormones

GLUCAGON HYDROCHLORIDE

glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1449G NP	1	1	..	47.74	38.30	GlucaGen Hypokit [NO]

glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5105Q DP	1	..	..	47.74	38.30	GlucaGen Hypokit [NO]

CALCIUM HOMEOSTASIS

PARATHYROID HORMONES AND ANALOGUES

Parathyroid hormones and analogues

TERIPARATIDE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required

Severe established osteoporosis
Treatment Phase: Initial treatment
Clinical criteria:
Patient must be at very high risk of fracture, AND
Patient must have a bone mineral density (BMD) T-score of -3.0 or less, AND
Patient must have had 2 or more fractures due to minimal trauma, AND
Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, AND
The treatment must be the sole PBS-subsidised agent, AND
The treatment must not exceed a lifetime maximum of 18 months therapy.
Treatment criteria:
Must be treated by a specialist; OR
Must be treated by a consultant physician.
A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.
If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with teriparatide is initiated.
If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with teriparatide is initiated.
Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months, strontium ranelate 2 g per day and zoledronic acid 5 mg per annum.
Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.

Note Details of accepted toxicities including severity can be found on the Department of Human Services website at www.humanservices.gov.au.

Authority required

Severe established osteoporosis
Treatment Phase: Continuing treatment
Clinical criteria:
Patient must have previously been issued with an authority prescription for this drug, AND
The treatment must not exceed a lifetime maximum of 18 months therapy.

Note Up to a maximum of 18 pens will be reimbursed through the PBS.

teriparatide 20 microgram injection, 2.4 mL cartridge

9411H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	411.13	38.30	Forteo [LY]

ANTI-PARATHYROID AGENTS

Calcitonin preparations

▪ SALCATONIN

Note The maximum quantities for salcatonin shown represent the number of individual ampoules and NOT multiples of the manufacturer's packs. The pack size for both strengths is five ampoules.

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

Restricted benefit

Symptomatic Paget disease of bone

Restricted benefit

Hypercalcaemia

Clinical criteria:

The treatment must be initiated in a hospital.

salcatonin 100 units/mL injection, 5 x 1 mL ampoules

2997R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	3	5	..	*144.00	38.30	Miacalcic 100 [NV]

▪ ANTIINFECTIVES FOR SYSTEMIC USE

▪ ANTIBACTERIALS FOR SYSTEMIC USE

TETRACYCLINES

Tetracyclines

▪ DOXYCYCLINE

Note Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

doxycycline 100 mg capsule: modified release, 7

2708M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	1	[B]1.54	12.91	12.54	[a] Mayne Pharma Doxycycline [YT]
			[B]2.96	14.33	12.54	[a] Doryx [YN]

doxycycline 100 mg capsule: modified release, 7

3322W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	[B]1.54	12.91	12.54	[a] Mayne Pharma Doxycycline [YT]
			[B]2.96	14.33	12.54	[a] Doryx [YN]

doxycycline 100 mg tablet, 7

2709N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	11.37	12.54	[a] Doxsig [RW] [a] Doxycycline AN [EA]	[a] Doxy-100 [ED] [a] Doxylin 100 [AF]

doxycycline 100 mg tablet, 7

3321T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	11.37	12.54	[a] Doxsig [RW] [a] Doxycycline AN [EA]	[a] Doxy-100 [ED] [a] Doxylin 100 [AF]

doxycycline 100 mg tablet, 7

5082L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	11.37	12.54	[a] Chem mart Doxycycline [CH] [a] GenRx Doxycycline [GX]	[a] Doxycycline Sandoz [HX] [a] Terry White Chemists Doxycycline [TW]

doxycycline 100 mg tablet, 7

9105F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	11.37	12.54	[a] Chem mart Doxycycline [CH]	[a] Doxycycline Sandoz [HX]

						[a] GenRx Doxycycline [GX]	[a] Terry White Chemists Doxycycline [TW]

▪ DOXYCYCLINE

Note Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

Restricted benefit

Urethritis

doxycycline 100 mg capsule: modified release, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	
2715X NP	1	..	[B]3.21	16.47	14.43	[a] Mayne Pharma Doxycycline [YT]	
			[B]9.00	22.26	14.43	[a] Doryx [YN]	

doxycycline 100 mg tablet, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10176N NP	1	..	..	13.26	14.43	[a] Doxycycline AN [EA]	[a] Doxylin 100 [AF]

doxycycline 100 mg tablet, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1800R NP	1	..	..	13.26	14.43	[a] GenRx Doxycycline [GX]

doxycycline 100 mg tablet, 7

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2714W NP	3	..	..	*13.26	14.43	[a] Doxsig [RW] [a] Doxycycline AN [EA]	[a] Doxy-100 [ED] [a] Doxylin 100 [AF]

doxycycline 100 mg tablet, 7

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9108J NP	3	..	..	*13.26	14.43	[a] Chem mart Doxycycline [CH] [a] Terry White Chemists Doxycycline [TW]	[a] Doxycycline Sandoz [HX]

▪ DOXYCYCLINE

Note Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

Restricted benefit

Severe acne

doxycycline 100 mg capsule: modified release, 7

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10777F	4	5	[B]6.16	*20.37	15.38	[a] Mayne Pharma Doxycycline [YT]
			[B]11.84	*26.05	15.38	[a] Doryx [YN]

doxycycline 100 mg tablet, 7

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10779H	4	5	..	*14.21	15.38	[a] Doxsig [RW] [a] Doxycycline AN [EA]	[a] Doxy-100 [ED] [a] Doxylin 100 [AF]

doxycycline 100 mg tablet, 7

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10781K	4	5	..	*14.21	15.38	[a] Chem mart Doxycycline [CH] [a] GenRx Doxycycline [GX]	[a] Doxycycline Sandoz [HX] [a] Terry White Chemists Doxycycline [TW]

▪ DOXYCYCLINE

Note Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hydrochloride), doxycycline tablet 100 mg (as monohydrate) and doxycycline capsule: modified release 100 mg (as hydrochloride) are equivalent for the purposes of substitution.

Restricted benefit

Pelvic inflammatory disease

doxycycline 100 mg capsule: modified release, 7

2703G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	4	..	[B]6.16	*20.37	15.38	[a] Mayne Pharma Doxycycline [YT]
			[B]11.84	*26.05	15.38	[a] Doryx [YN]

doxycycline 100 mg tablet, 7

2702F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	..	..	*14.21	15.38	[a] Doxsig [RW]	[a] Doxy-100 [ED]
						[a] Doxycycline AN [EA]	[a] Doxylin 100 [AF]

doxycycline 100 mg tablet, 7

9107H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	..	..	*14.21	15.38	[a] Chem mart Doxycycline [CH]	[a] Doxycycline Sandoz [HX]
						[a] GenRx Doxycycline [GX]	[a] Terry White Chemists Doxycycline [TW]

▪ DOXYCYCLINE

Note Pharmaceutical benefits that have the forms doxycycline tablet 50 mg (as hydrochloride), doxycycline tablet 50 mg (as monohydrate) and doxycycline capsule: modified release 50 mg (as hydrochloride) are equivalent for the purposes of substitution.

Restricted benefit
Bronchiectasis
Population criteria:
Patient must be aged 8 years or older.

Restricted benefit
Chronic bronchitis
Population criteria:
Patient must be aged 8 years or older.

Restricted benefit
Severe acne

doxycycline 50 mg capsule: modified release, 25

2707L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	[B]2.59	14.70	13.28	[a] Mayne Pharma Doxycycline [YT]
			[B]5.01	17.12	13.28	[a] Doryx [YN]

doxycycline 50 mg tablet, 25

2711Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.11	13.28	[a] Doxy-50 [ED]	[a] Doxycycline AN [EA]
						[a] Doxylin 50 [AF]	

doxycycline 50 mg tablet, 25

9106G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.11	13.28	[a] Chem mart Doxycycline [CH]	[a] Doxycycline Sandoz [HX]
						[a] Frakas [RW]	[a] GenRx Doxycycline [GX]
						[a] Terry White Chemists Doxycycline [TW]	

▪ MINOCYCLINE

Caution There are concerns about the incidence of benign intracranial hypertension associated with this drug.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit
Severe acne
Clinical criteria:
The condition must not be responding to other tetracyclines.

minocycline 50 mg tablet, 60

1616C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	17.92	19.09	[a] Akamin 50 [AF]
			[B]1.65	19.57	19.09	[a] Minomycin-50 [QA]

BETA-LACTAM ANTIBACTERIALS, PENICILLINS

Penicillins with extended spectrum

▪ AMOXYCILLIN

amoxycillin 100 mg/mL oral liquid: powder for, 20 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1888J NP	‡1	1	[S]0.53	#17.28	18.28	Amoxil [AS]

amoxycillin 100 mg/mL oral liquid: powder for, 20 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3310F DP	‡1	..	[S]0.53	#17.28	18.28	Amoxil [AS]

amoxycillin 125 mg/5 mL oral liquid: powder for, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1886G NP	‡1	1	..	#13.66	15.19	[a] Alphamox 125 [AF] [a] APO-Amoxycillin [TX] [a] Chem mart Amoxycillin [CH] [a] Terry White Chemists Amoxycillin [TW]	[a] Amoxycillin Sandoz [SZ] [a] Bgramin [FM] [a] Ranmoxy [RA]
			[B]3.46	#17.12	15.19	[a] Amoxil [AS]	

amoxycillin 125 mg/5 mL oral liquid: powder for, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3302T DP	‡1	..	..	#13.66	15.19	[a] Alphamox 125 [AF] [a] APO-Amoxycillin [TX] [a] Chem mart Amoxycillin [CH] [a] Terry White Chemists Amoxycillin [TW]	[a] Amoxycillin Sandoz [SZ] [a] Bgramin [FM] [a] Ranmoxy [RA]
			[B]3.46	#17.12	15.19	[a] Amoxil [AS]	

amoxycillin 250 mg capsule, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1884E NP MW	1	1	..	11.09	12.26	[a] Alphamox 250 [AF] [a] Amoxycillin-GA [FM] [a] Amoxycillin Sandoz [SZ] [a] Chem mart Amoxycillin [CH] [a] Terry White Chemists Amoxycillin [TW]	[a] Amoxycillin AN [EA] [a] Amoxycillin Ranbaxy [RA] [a] APO-Amoxycillin [TX] [a] Cilamox [QA] [a] Yomax 250 [DO]
			[B]3.49	14.58	12.26	[a] Amoxil [AS]	

amoxycillin 250 mg capsule, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3301R DP	1	..	..	11.09	12.26	[a] Alphamox 250 [AF] [a] Amoxycillin-GA [FM] [a] Amoxycillin Sandoz [SZ] [a] Chem mart Amoxycillin [CH] [a] Terry White Chemists Amoxycillin [TW]	[a] Amoxycillin AN [EA] [a] Amoxycillin Ranbaxy [RA] [a] APO-Amoxycillin [TX] [a] Cilamox [QA] [a] Yomax 250 [DO]
			[B]3.49	14.58	12.26	[a] Amoxil [AS]	

amoxycillin 250 mg/5 mL oral liquid: powder for, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1887H NP	‡1	1	..	#13.93	15.46	[a] Alphamox 250 [AF] [a] APO-Amoxycillin [TX] [a] Chem mart Amoxycillin [CH] [a] Ranmoxy [RA]	[a] Amoxycillin Sandoz [SZ] [a] Bgramin [FM] [a] Cilamox [QA] [a] Terry White Chemists Amoxycillin [TW]
			[B]3.56	#17.49	15.46	[a] Amoxil Forte [AS]	

amoxycillin 250 mg/5 mL oral liquid: powder for, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3393N DP	‡1	..	..	#13.93	15.46	[a] Alphamox 250 [AF] [a] APO-Amoxycillin [TX] [a] Chem mart Amoxycillin [CH] [a] Ranmoxy [RA]	[a] Amoxycillin Sandoz [SZ] [a] Bgramin [FM] [a] Cilamox [QA] [a] Terry White Chemists Amoxycillin [TW]
			[B]3.56	#17.49	15.46	[a] Amoxil Forte [AS]	

amoxycillin 500 mg capsule, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1889K NP MW	1	1	..	11.75	12.92	[a] Alphamox 500 [AF]	[a] Amoxycillin AN [EA]

					[a] Amoxycillin-GA [FM]	[a] Amoxycillin generichealth 500 [GQ]
					[a] Amoxycillin Ranbaxy [RA]	[a] Amoxycillin Sandoz [SZ]
					[a] APO-Amoxycillin [TX]	[a] Chem mart Amoxycillin [CH]
					[a] Cilamox [QA]	[a] Terry White Chemists Amoxycillin [TW]
					[a] Yomax 500 [DO]	
		[B]3.76	15.51	12.92	[a] Amoxil [AS]	

amoxycillin 500 mg capsule, 20

3300Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	11.75	12.92	[a] Alphamox 500 [AF]	[a] Amoxycillin AN [EA]
						[a] Amoxycillin-GA [FM]	[a] Amoxycillin generichealth 500 [GQ]
						[a] Amoxycillin Ranbaxy [RA]	[a] Amoxycillin Sandoz [SZ]
						[a] APO-Amoxycillin [TX]	[a] Chem mart Amoxycillin [CH]
						[a] Cilamox [QA]	[a] Terry White Chemists Amoxycillin [TW]
						[a] Yomax 500 [DO]	
			[B]3.76	15.51	12.92	[a] Amoxil [AS]	

amoxycillin 500 mg/5 mL oral liquid: powder for, 100 mL

5225B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	‡1	..	..	#14.88	16.41	Maxamox [SZ]

amoxycillin 500 mg/5 mL oral liquid: powder for, 100 mL

8705E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	1	..	#14.88	16.41	Maxamox [SZ]

▪ AMOXYCILLIN

Restricted benefit

Chronic bronchitis

Clinical criteria:

Patient must have acute exacerbations of the condition.

amoxycillin 1 g tablet, 14

8581P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	1	..	11.79	12.96	[a] Amoxycillin Sandoz [BG]
			[B]0.36	12.15	12.96	[a] Maxamox [SZ]

▪ AMOXYCILLIN

Authority required

Infection suspected or proven to be due to a susceptible organism

Clinical criteria:

The treatment must be for patients who require a liquid formulation and in whom the syrup formulations are unsuitable.

amoxycillin 100 mg/mL oral liquid: powder for, 20 mL

9714G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	1	..	#17.28	18.81	Amoxil [AS]

▪ AMPICILLIN

ampicillin 1 g injection, 5 vials

2977Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	15.27	16.44	[a] Ampicyn [AF]	[a] Austrapen [AL]

ampicillin 1 g injection, 5 vials

3314K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	15.27	16.44	[a] Ampicyn [AF]	[a] Austrapen [AL]

ampicillin 500 mg injection, 5 vials

2390T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	1	..	13.37	14.54	Austrapen [AL]

ampicillin 500 mg injection, 5 vials

3313J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	13.37	14.54	Austrapen [AL]

Beta-lactamase sensitive penicillins

▪ BENZATHINE BENZYLPENICILLIN

BENZATHINE BENZYLPENICILLIN Injection 900 mg in 2.3 mL single use pre-filled syringe, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2267H NP	1	..	..	293.33	38.30	Bicillin L-A [PF]

BENZATHINE BENZYLPENICILLIN Injection 900 mg in 2.3 mL single use pre-filled syringe, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5027N DP	1	..	..	293.33	38.30	Bicillin L-A [PF]

▪ BENZYLPENICILLIN

benzylpenicillin 3 g injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2647H NP	10	..	..	*93.03	38.30	BenPen [CS]

benzylpenicillin 3 g injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3399X DP	10	..	..	*93.03	38.30	BenPen [CS]

benzylpenicillin 600 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1775K NP MW	10	1	..	*58.23	38.30	BenPen [CS]

benzylpenicillin 600 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3398W DP	10	..	..	*58.23	38.30	BenPen [CS]

▪ PHENOXYMETHYLPENICILLIN

phenoxymethylpenicillin 125 mg/5 mL oral liquid: powder for, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5024K DP	2	..	..	*#19.82	21.35	Phenoxymethylpenicillin-AFT [AE]

phenoxymethylpenicillin 125 mg/5 mL oral liquid: powder for, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8976K NP	2	1	..	*#19.82	21.35	Phenoxymethylpenicillin-AFT [AE]

phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5012T DP	2	..	..	*23.63	24.80	[a] Cilicaine V [FM]
			[B]1.66	*25.29	24.80	[a] Abbocillin-V [QA]

phenoxymethylpenicillin 150 mg/5 mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9143F NP	2	1	..	*23.63	24.80	[a] Cilicaine V [FM]
			[B]1.66	*25.29	24.80	[a] Abbocillin-V [QA]

phenoxymethylpenicillin 250 mg capsule, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1789E NP	1	..	..	14.54	15.71	Cilicaine VK [FM]	LPV [IA]

phenoxymethylpenicillin 250 mg capsule, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3363B DP	1	..	..	14.54	15.71	Cilicaine VK [FM]	LPV [IA]

phenoxymethylpenicillin 250 mg tablet, 25

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1787C NP	2	..	..	*14.69	15.86	Abbocillin-VK Filmtab [QA]

phenoxymethylpenicillin 250 mg tablet, 25

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3360W DP	2	..	..	*14.69	15.86	Abbocillin-VK Filmtab [QA]

phenoxymethylpenicillin 250 mg/5 mL oral liquid: powder for, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5029Q DP	2	..	..	*#22.06	23.59	Phenoxymethylpenicillin-AFT [AE]

phenoxymethylpenicillin 250 mg/5 mL oral liquid: powder for, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8977L NP	2	1	..	*#22.06	23.59	Phenoxymethylpenicillin-AFT [AE]

phenoxymethylpenicillin 500 mg capsule, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2965C NP	1	..	..	16.55	17.72	Cilicaine VK [FM]	LPV [IA]

phenoxymethylpenicillin 500 mg capsule, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3364C DP	1	..	..	16.55	17.72	Cilicaine VK [FM]	LPV [IA]

phenoxymethylpenicillin 500 mg tablet, 25

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3028J NP	2	..	..	*16.73	17.90	Abbocillin-VK Filmtab [QA]

phenoxymethylpenicillin 500 mg tablet, 25

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3361X DP	2	..	..	*16.73	17.90	Abbocillin-VK Filmtab [QA]

▪ PHENOXYMETHYLPENICILLIN

Restricted benefit

Recurrent streptococcal infections (including rheumatic fever)

Clinical criteria:

The treatment must be for prophylaxis.

phenoxymethylpenicillin 250 mg capsule, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1705R NP	1	5	..	14.54	15.71	Cilicaine VK [FM]	LPV [IA]

phenoxymethylpenicillin 250 mg tablet, 25

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1703P NP	2	5	..	*14.69	15.86	Abbocillin-VK Filmtab [QA]

▪ PROCAINE PENICILLIN

procaine penicillin 1.5 g/3.4 mL injection, 5 x 3.4 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1794K NP	1	..	..	84.51	38.30	Cilicaine [QA]

procaine penicillin 1.5 g/3.4 mL injection, 5 x 3.4 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3371K DP	1	..	..	84.51	38.30	Cilicaine [QA]

Beta-lactamase resistant penicillins

▪ DICLOXACILLIN

Restricted benefit

Serious staphylococcal infection

dicloxacillin 250 mg capsule, 24

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5096F DP	1	..	..	15.93	17.10	Distaph 250 [AF]

dicloxacillin 500 mg capsule, 24

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5097G DP	1	..	..	20.06	21.23	Distaph 500 [AF]

▪ DICLOXACILLIN

Restricted benefit

Serious staphylococcal infection

dicloxacillin 250 mg capsule, 24

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8121K NP MW	1	..	..	15.93	17.10	Distaph 250 [AF]

dicloxacillin 500 mg capsule, 24

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8122L NP MW	1	..	..	20.06	21.23	Distaph 500 [AF]

▪ DICLOXACILLIN

Authority required (STREAMLINED)
6188
Osteomyelitis

dicloxacillin 500 mg capsule, 24

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10790X	2	1	..	*29.71	30.88	Distaph 500 [AF]

▪ FLUCLOXACILLIN

Caution Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

flucloxacillin 500 mg injection, 5 vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1524F NP	1	..	..	13.28	14.45	Flubiclox [JU]

flucloxacillin 500 mg injection, 5 vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5094D DP	1	..	..	13.28	14.45	Flubiclox [JU]

▪ FLUCLOXACILLIN

Caution Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

flucloxacillin 1 g injection, 5 vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1525G NP	1	1	..	22.43	23.60	[a] Flubiclox [JU] [a] Hospira Pty Limited [HH]	[a] Flucil [AS]

flucloxacillin 1 g injection, 5 vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5095E DP	1	..	..	22.43	23.60	[a] Flubiclox [JU] [a] Hospira Pty Limited [HH]	[a] Flucil [AS]

▪ FLUCLOXACILLIN

Caution Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

Note Pharmaceutical benefits that have the form flucloxacillin 1 g injection in a pack size of 5 can be substituted for a pack size of 10 in the case of a shortage.

flucloxacillin 1 g injection, 10 vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10605E NP	0.5	1	..	*26.85	28.13	[a] Hospira Pty Limited [HH]

flucloxacillin 1 g injection, 10 vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10609J DP	0.5	..	..	*26.85	28.13	[a] Hospira Pty Limited [HH]

▪ FLUCLOXACILLIN

Caution Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

Restricted benefit
Serious staphylococcal infection

flucloxacillin 250 mg capsule, 24

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1526H NP MW	1	..	..	14.57	15.74	[a] APO-Flucloxacillin [TX] [a] Staphylex 250 [AF]	[a] Flopen [AS]

flucloxacillin 500 mg capsule, 24

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1527J NP MW	1	..	..	19.11	20.28	[a] APO-Flucloxacillin [TX] [a] Staphylex 500 [AF]	[a] Flopen [AS]

▪ FLUCLOXACILLIN

Caution Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

Restricted benefit

Serious staphylococcal infection

flucloxacillin 125 mg/5 mL oral liquid: powder for, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5257Q DP	‡1	..	..	#19.20	20.73	Flucil [LN]

flucloxacillin 250 mg capsule, 24

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5090X DP	1	..	..	14.57	15.74	[a] APO-Flucloxacillin [TX] [a] Staphylex 250 [AF]	[a] Flopen [AS]

flucloxacillin 250 mg/5 mL oral liquid: powder for, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5258R DP	‡1	..	..	#22.27	23.80	Flucil [LN]

flucloxacillin 500 mg capsule, 24

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5091Y DP	1	..	..	19.11	20.28	[a] APO-Flucloxacillin [TX] [a] Staphylex 500 [AF]	[a] Flopen [AS]

▪ FLUCLOXACILLIN

Caution Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

Restricted benefit

Serious staphylococcal infection

flucloxacillin 125 mg/5 mL oral liquid: powder for, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9149M NP	‡1	1	..	#19.20	20.73	Flucil [LN]

flucloxacillin 250 mg/5 mL oral liquid: powder for, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9150N NP	‡1	1	..	#22.27	23.80	Flucil [LN]

▪ FLUCLOXACILLIN

Caution Severe cholestatic jaundice has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

Authority required (STREAMLINED)

6169

Osteomyelitis

flucloxacillin 500 mg capsule, 24

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10788T	2	1	..	*27.81	28.98	[a] APO-Flucloxacillin [TX] [a] Staphylex 500 [AF]	[a] Flopen [AS]

Combinations of penicillins, incl. beta-lactamase inhibitors

▪ AMOXYCILLIN + CLAVULANIC ACID

Caution Hepatotoxicity has been reported with this drug.

Restricted benefit

Infection where resistance to amoxycillin is suspected

Restricted benefit

Infections where resistance to amoxycillin is proven

amoxycillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL oral liquid: powder for, 75 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1892N NP	‡1	1	..	#14.26	15.79	[a] APO-Amoxycillin and Clavulanic Acid 125/31.25 [TX] [a] GA-Amclav 125/31.25 [FM]	[a] Curam [SZ]

			[B]3.45	#17.71	15.79	[a] Augmentin [AS]	

amoxycillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL oral liquid: powder for, 60 mL

8319W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	1	..	#14.78	16.31	[a] APO-Amoxycillin and Clavulanic Acid 400/57 [TX] [a] GA-Amclav Forte 400/57 [FM]	[a] Curam Duo [SZ]
			[B]4.84	#19.62	16.31	[a] Augmentin Duo 400 [AS]	

amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10

1891M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	1	..	12.37	13.54	[a] AlphaClav Duo [AF] [a] APO-Amoxycillin/ Clavulanic Acid 500/125 [TX] [a] GA-Amclav 500/125 [FM] [a] Pharmacor AmoxyClav 500/125 [CR]	[a] Amoxyclav AN 500/125 [EA] [a] Curam Duo 500/125 [SZ] [a] Moxiclav Duo 500/125 [QA]
			[B]4.87	17.24	13.54	[a] Augmentin Duo [AS]	

amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10

8254K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	13.19	14.36	[a] AlphaClav Duo Forte [AF] [a] AmoxyClav GH 875/125 [GQ] [a] APO-Amoxycillin and Clavulanic Acid [TX] [a] Clavam 875 mg/125 mg [CR] [a] GA-Amclav Forte 875/125 [FM] [a] Terry White Chemists Amoxycillin and Clavulanic Acid [TW]	[a] Amoxyclav AN 875/125 [EA] [a] AmoxyClav RBX 875/125 [RA] [a] Chem mart Amoxycillin and Clavulanic Acid [CH] [a] Curam Duo Forte 875/125 [SZ] [a] Moxiclav Duo Forte 875/125 [QA]
			[B]6.24	19.43	14.36	[a] Augmentin Duo forte [AS]	

▪ AMOXYCILLIN + CLAVULANIC ACID

Caution Hepatotoxicity has been reported with this drug.

Restricted benefit

Infection where resistance to amoxycillin is suspected

Restricted benefit

Infections where resistance to amoxycillin is proven

amoxycillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL oral liquid: powder for, 75 mL

5009P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	‡1	..	..	#14.26	15.79	[a] APO-Amoxycillin and Clavulanic Acid 125/31.25 [TX] [a] GA-Amclav 125/31.25 [FM]	[a] Curam [SZ]
			[B]3.45	#17.71	15.79	[a] Augmentin [AS]	

amoxycillin 400 mg/5 mL + clavulanic acid 57 mg/5 mL oral liquid: powder for, 60 mL

5011R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	‡1	..	..	#14.78	16.31	[a] APO-Amoxycillin and Clavulanic Acid 400/57 [TX] [a] GA-Amclav Forte 400/57 [FM]	[a] Curam Duo [SZ]
			[B]4.84	#19.62	16.31	[a] Augmentin Duo 400 [AS]	

amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10

5008N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	12.37	13.54	[a] AlphaClav Duo [AF] [a] APO-Amoxycillin/ Clavulanic Acid 500/125 [TX] [a] GA-Amclav 500/125 [FM] [a] Pharmacor AmoxyClav 500/125 [CR]	[a] Amoxyclav AN 500/125 [EA] [a] Curam Duo 500/125 [SZ] [a] Moxiclav Duo 500/125 [QA]
			[B]4.87	17.24	13.54	[a] Augmentin Duo [AS]	

amoxycillin 875 mg + clavulanic acid 125 mg tablet, 10

5006L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	13.19	14.36	[a] AlphaClav Duo Forte [AF] [a] AmoxyClav GH 875/125 [GQ] [a] APO-Amoxycillin and Clavulanic Acid [TX]	[a] Amoxyclav AN 875/125 [EA] [a] AmoxyClav RBX 875/125 [RA] [a] Chem mart Amoxycillin and Clavulanic Acid [CH]

				[a] Clavam 875 mg/125 mg [CR] [a] GA-Amclav Forte 875/125 [FM] [a] Terry White Chemists Amoxycillin and Clavulanic Acid [TW]	[a] Curam Duo Forte 875/125 [SZ] [a] Moxiclav Duo Forte 875/125 [QA]
	[B]6.24	19.43	14.36	[a] Augmentin Duo forte [AS]	

▪ TICARCILLIN + CLAVULANIC ACID

Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

ticarcillin 3 g + clavulanic acid 100 mg injection, 1 x 3.1 g vial

10125X (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10	..	..	*146.03	38.30	Timentin [AS]

▪ TICARCILLIN + CLAVULANIC ACID

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

Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Restricted benefit

Septicaemia, suspected

Restricted benefit

Septicaemia, proven

ticarcillin 3 g + clavulanic acid 100 mg injection, 1 x 3.1 g vial

10113G (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10	..	..	*146.03	38.30	Timentin [AS]

OTHER BETA-LACTAM ANTIBACTERIALS

First-generation cephalosporins

▪ CEPHALEXIN

cephalexin 125 mg/5 mL oral liquid: powder for, 100 mL

3094W (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	1	..	#14.11	15.64	[a] APO-Cephalexin [TX] [a] Chem mart Cephalexin [CH] [a] Ibilex 125 [AF]	[a] Cefalexin Sandoz [SZ] [a] Ialex [LN] [a] Terry White Chemists Cephalexin [TW]
		[B]4.15	#18.26	15.64	[a] Keflex [AS]	

cephalexin 125 mg/5 mL oral liquid: powder for, 100 mL

3319Q (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	..	..	#14.11	15.64	[a] APO-Cephalexin [TX] [a] Chem mart Cephalexin [CH] [a] Ibilex 125 [AF]	[a] Cefalexin Sandoz [SZ] [a] Ialex [LN] [a] Terry White Chemists Cephalexin [TW]
		[B]4.15	#18.26	15.64	[a] Keflex [AS]	

cephalexin 250 mg capsule, 20

3058Y (NP) (MW)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	11.29	12.46	[a] APO-Cephalexin [TX] [a] Cephalex 250 [CR] [a] Cephalexin generichealth [GQ] [a] Cilex [ED] [a] Ibilex 250 [AF] [a] Terry White Chemists Cephalexin [TW]	[a] Cefalexin Sandoz [SZ] [a] Cephalexin AN [EA] [a] Chem mart Cephalexin [CH] [a] Ialex [LN] [a] Rancef [RA]
		[B]3.76	15.05	12.46	[a] Keflex [AS]	

cephalexin 250 mg capsule, 20

3317N (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	11.29	12.46	[a] APO-Cephalexin [TX] [a] Cephalex 250 [CR] [a] Cephalexin generichealth [GQ]	[a] Cefalexin Sandoz [SZ] [a] Cephalexin AN [EA] [a] Chem mart Cephalexin [CH]

						[a] Cilex [ED] [a] Ibilex 250 [AF] [a] Terry White Chemists Cephalexin [TW]	[a] Ialex [LN] [a] Rancef [RA]
			[B]3.76	15.05	12.46	[a] Keflex [AS]	

cephalexin 250 mg/5 mL oral liquid: powder for, 100 mL

3095X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	1	..	#14.63	16.16	[a] APO-Cephalexin [TX] [a] Chem mart Cephalexin [CH] [a] Ibilex 250 [AF]	[a] Cefalexin Sandoz [SZ] [a] Ialex [LN] [a] Terry White Chemists Cephalexin [TW]
			[B]5.69	#20.32	16.16	[a] Keflex [AS]	

cephalexin 250 mg/5 mL oral liquid: powder for, 100 mL

3320R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	‡1	..	..	#14.63	16.16	[a] APO-Cephalexin [TX] [a] Chem mart Cephalexin [CH] [a] Ibilex 250 [AF]	[a] Cefalexin Sandoz [SZ] [a] Ialex [LN] [a] Terry White Chemists Cephalexin [TW]
			[B]5.69	#20.32	16.16	[a] Keflex [AS]	

cephalexin 500 mg capsule, 20

3119E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	1	..	11.99	13.16	[a] APO-Cephalexin [TX] [a] Cephalex 500 [CR] [a] Cephalexin generichealth [GQ] [a] Cilex [ED] [a] Ibilex 500 [AF] [a] Terry White Chemists Cephalexin [TW]	[a] Cefalexin Sandoz [SZ] [a] Cephalexin AN [EA] [a] Chem mart Cephalexin [CH] [a] Ialex [LN] [a] Rancef [RA]
			[B]5.47	17.46	13.16	[a] Keflex [AS]	

cephalexin 500 mg capsule, 20

3318P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	11.99	13.16	[a] APO-Cephalexin [TX] [a] Cephalex 500 [CR] [a] Cephalexin generichealth [GQ] [a] Cilex [ED] [a] Ibilex 500 [AF] [a] Terry White Chemists Cephalexin [TW]	[a] Cefalexin Sandoz [SZ] [a] Cephalexin AN [EA] [a] Chem mart Cephalexin [CH] [a] Ialex [LN] [a] Rancef [RA]
			[B]5.47	17.46	13.16	[a] Keflex [AS]	

▪ CEPHALEXIN

Authority required (STREAMLINED)

6188

Osteomyelitis

cephalexin 500 mg capsule, 20

10778G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*13.57	14.74	[a] APO-Cephalexin [TX] [a] Cephalex 500 [CR] [a] Cephalexin generichealth [GQ] [a] Cilex [ED] [a] Ibilex 500 [AF] [a] Terry White Chemists Cephalexin [TW]	[a] Cefalexin Sandoz [SZ] [a] Cephalexin AN [EA] [a] Chem mart Cephalexin [CH] [a] Ialex [LN] [a] Rancef [RA]
			[B]10.94	*24.51	14.74	[a] Keflex [AS]	

▪ CEPHALEXIN

Authority required (STREAMLINED)

4243

Prophylaxis of urinary tract infection

cephalexin 250 mg capsule, 20

2655R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*12.17	13.34	[a] APO-Cephalexin [TX] [a] Cephalex 250 [CR] [a] Cephalexin generichealth [GQ]	[a] Cefalexin Sandoz [SZ] [a] Cephalexin AN [EA] [a] Chem mart Cephalexin [CH]

					[a] Cilex [ED] [a] Ibilex 250 [AF] [a] Terry White Chemists Cephalexin [TW]	[a] Ialex [LN] [a] Rancef [RA]
	[B]7.52	*19.69	13.34	[a] Keflex [AS]		

▪ CEPHALOTHIN

cephalothin 1 g injection, 10 vials

2964B (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	39.14	38.30	Hospira Pty Limited [HH]

cephalothin 1 g injection, 10 vials

3376Q (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	39.14	38.30	Hospira Pty Limited [HH]

▪ CEPHAZOLIN

Restricted benefit
Cellulitis

cephazolin 2 g injection, 1 vial

5479J (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10	..	..	*25.23	26.40	Cephazolin Alphapharm [AF]

cephazolin 500 mg injection, 5 vials

5477G (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*16.73	17.90	Cefazolin-AFT [AE]

▪ CEPHAZOLIN

Note For item codes 5478H and 1799Q, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

Restricted benefit
Cellulitis

cephazolin 1 g injection, 10 vials

5478H (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	16.89	18.06	[a] Cefazolin Sandoz [SZ]

cephazolin 1 g injection, 5 vials

1799Q (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	..	..	*16.91	18.08	[a] Cefazolin-AFT [AE]	[a] Hospira Cefazolin Sodium [HH]

▪ CEPHAZOLIN

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

Restricted benefit
Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Restricted benefit
Septicaemia, suspected

Restricted benefit
Septicaemia, proven

cephazolin 2 g injection, 1 vial

9326W (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10	..	..	*25.23	26.40	Cephazolin Alphapharm [AF]

cephazolin 500 mg injection, 5 vials

1256D (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*16.73	17.90	Cefazolin-AFT [AE]

▪ CEPHAZOLIN

Note For item codes 1257E and 1797N, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Restricted benefit
Septicaemia, suspected

Restricted benefit
Septicaemia, proven

cephazolin 1 g injection, 10 vials

1257E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	16.89	18.06	[a] Cefazolin Sandoz [SZ]

cephazolin 1 g injection, 5 vials

1797N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*16.91	18.08	[a] Cefazolin-AFT [AE]	[a] Hospira Cefazolin Sodium [HH]

Second-generation cephalosporins

▪ CEFACLOR

Caution Serum sickness-like reactions have been reported with this drug, especially in children.

cefaclor 125 mg/5 mL oral liquid: powder for, 100 mL

2460L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	1	..	#15.40	16.93	[a] Aclor 125 [QA] [a] Keflor [AF]	[a] APO-Cefaclor [TX]
			[B]5.10	#20.50	16.93	[a] Ceclor [AS]	

cefaclor 125 mg/5 mL oral liquid: powder for, 100 mL

5046N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	‡1	..	..	#15.40	16.93	[a] Aclor 125 [QA] [a] Keflor [AF]	[a] APO-Cefaclor [TX]
			[B]5.10	#20.50	16.93	[a] Ceclor [AS]	

cefaclor 250 mg/5 mL oral liquid: powder for, 75 mL

2461M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	1	..	#15.58	17.11	[a] Aclor 250 [QA] [a] Keflor [AF]	[a] APO-Cefaclor [TX]
			[B]5.31	#20.89	17.11	[a] Ceclor [AS]	

cefaclor 250 mg/5 mL oral liquid: powder for, 75 mL

5047P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	‡1	..	..	#15.58	17.11	[a] Aclor 250 [QA] [a] Keflor [AF]	[a] APO-Cefaclor [TX]
			[B]5.31	#20.89	17.11	[a] Ceclor [AS]	

cefaclor 375 mg tablet: modified release, 10

1169M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	13.75	14.92	[a] APO-Cefaclor CD [TX] [a] Cefaclor GH [GQ] [a] Karlor CD [LN] [a] Ozcef [RA]	[a] Cefaclor-GA [EA] [a] Chem mart Cefaclor CD [CH] [a] Keflor CD [AF] [a] Terry White Chemists Cefaclor CD [TW]
			[B]6.26	20.01	14.92	[a] Ceclor CD [AS]	

cefaclor 375 mg tablet: modified release, 10

5045M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	13.75	14.92	[a] APO-Cefaclor CD [TX] [a] Cefaclor GH [GQ] [a] Karlor CD [LN] [a] Ozcef [RA]	[a] Cefaclor-GA [EA] [a] Chem mart Cefaclor CD [CH] [a] Keflor CD [AF] [a] Terry White Chemists Cefaclor CD [TW]
			[B]6.26	20.01	14.92	[a] Ceclor CD [AS]	

▪ CEFUROXIME

CEFUROXIME AXETIL Powder for oral suspension 125 mg (base) per 5 mL, 70 mL, 1

2002J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	‡1	..	..	#21.67	23.20	Zinnat [AS]

CEFUROXIME AXETIL Powder for oral suspension 125 mg (base) per 5 mL, 70 mL, 1

5499K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	#21.67	23.20	Zinnat [AS]

cefuroxime 250 mg tablet, 14

5052X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	20.51	21.68	Zinnat [AS]

cefuroxime 250 mg tablet, 14

8292K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	20.51	21.68	Zinnat [AS]

Third-generation cephalosporins

▪ CEFOTAXIME

Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

CEFOTAXIME Powder for injection 2 g, 10

1769D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	34.07	35.24	Hospira Pty Limited [HH]

▪ CEFOTAXIME

Note For item codes 5048Q and 1768C, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

CEFOTAXIME Powder for injection 1 g, 10

1768C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	23.21	24.38	[a] Hospira Pty Limited [HH]

cefotaxime 1 g injection, 1 vial

5048Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	10	..	..	*23.23	24.40	[a] Cefotaxime Sandoz [SZ]

▪ CEFOTAXIME

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

Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Restricted benefit

Septicaemia, suspected

Restricted benefit

Septicaemia, proven

CEFOTAXIME Powder for injection 2 g, 10

1759N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	34.07	35.24	Hospira Pty Limited [HH]

▪ CEFOTAXIME

Note For item codes 1085D and 1758M, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

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

Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Restricted benefit

Septicaemia, suspected

Restricted benefit

Septicaemia, proven

CEFOTAXIME Powder for injection 1 g, 10

1758M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	23.21	24.38	[a] Hospira Pty Limited [HH]

cefotaxime 1 g injection, 1 vial

1085D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	10	..	..	*23.23	24.40	[a] Cefotaxime Sandoz [SZ]

▪ CEFTRIAXONE

Restricted benefit

Gonorrhoea

ceftriaxone 500 mg injection, 1 vial

9058R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	11.48	12.65	Ceftriaxone-AFT [AE]

▪ CEFTRIAXONE

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

Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Restricted benefit

Septicaemia, suspected

Restricted benefit

Septicaemia, proven

ceftriaxone 2 g injection, 1 vial

1785Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	..	..	*21.58	22.75	[a] Ceftriaxone-AFT [AE] [a] Hospira Ceftriaxone [HH]	[a] Ceftriaxone Alphapharm [AF]

ceftriaxone 500 mg injection, 1 vial

1783W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	5	..	..	*15.73	16.90	Ceftriaxone-AFT [AE]

▪ CEFTRIAXONE

Note For item codes 1784X and 1788D, pharmaceutical benefits that have the form powder for injection 1 g are equivalent for the purposes of substitution.

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

Restricted benefit

Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

Restricted benefit

Septicaemia, suspected

Restricted benefit

Septicaemia, proven

CEFTRIAXONE Powder for injection 1 g, 5

1788D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	16.44	17.61	[a] Ceftriaxone Alphapharm [AF]	[a] Max Pharma Ceftriaxone [GQ]

ceftriaxone 1 g injection, 1 vial

1784X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	..	..	*16.43	17.60	[a] Ceftriaxone-AFT [AE] [a] Hospira Ceftriaxone [HH]	[a] Ceftriaxone Sandoz [SZ]

Fourth-generation cephalosporins

▪ CEFEPIME

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

Authority required

Febrile neutropenia

CEFEPIME Powder for injection 1 g (as hydrochloride), 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8315P NP	10	..	..	*59.43	38.30	[a] Cefepime-AFT [AE] [a] Cefepime Sandoz [SZ] [a] Omegapharm Pty Ltd [OE]	[a] Cefepime Alphapharm [AF] [a] DBL Cefepime [HH]

CEFEPIME Powder for injection 2 g (as hydrochloride), 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8316Q NP	10	..	..	*103.73	38.30	[a] Cefepime-AFT [AE] [a] Cefepime Sandoz [SZ] [a] Omegapharm Pty Ltd [OE]	[a] Cefepime Alphapharm [AF] [a] DBL Cefepime [HH]

SULFONAMIDES AND TRIMETHOPRIM

Trimethoprim and derivatives

- **TRIMETHOPRIM**

trimethoprim 300 mg tablet, 7

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2922T NP	1	1	..	12.12	13.29	[a] Alprim [AF]
			[B]1.65	13.77	13.29	[a] Triprim [RW]

- **TRIMETHOPRIM**

Authority required (STREAMLINED)

4243

Prophylaxis of urinary tract infection

trimethoprim 300 mg tablet, 7

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2666H	2	2	..	*13.83	15.00	[a] Alprim [AF]
			[B]3.30	*17.13	15.00	[a] Triprim [RW]

- **TRIMETHOPRIM**

Restricted benefit

Prostatitis

trimethoprim 300 mg tablet, 7

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10785P	4	..	..	*17.21	18.38	[a] Alprim [AF]
			[B]6.60	*23.81	18.38	[a] Triprim [RW]

Combinations of sulfonamides and trimethoprim, incl. derivatives

- **TRIMETHOPRIM + SULFAMETHOXAZOLE**

Caution There is an increased risk of severe adverse reactions with this combination in the elderly.

trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2951H NP	1	1	..	12.87	14.04	[a] Bactrim DS [RO]	[a] Resprim Forte [AF]
			[B]3.39	16.26	14.04	[a] Septrin Forte [RW]	

trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3390K DP	1	..	..	12.87	14.04	[a] Bactrim DS [RO]	[a] Resprim Forte [AF]
			[B]3.39	16.26	14.04	[a] Septrin Forte [RW]	

trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3103H NP	‡1	1	..	12.60	13.77	Bactrim [RO]
			[B]3.70	16.30	13.77	Septrin [RW]

trimethoprim 40 mg/5 mL + sulfamethoxazole 200 mg/5 mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3391L DP	‡1	..	..	12.60	13.77	Bactrim [RO]
			[B]3.70	16.30	13.77	Septrin [RW]

- **TRIMETHOPRIM + SULFAMETHOXAZOLE**

Caution There is an increased risk of severe adverse reactions with this combination in the elderly.

Authority required (STREAMLINED)

6201
Prophylaxis of Pneumocystis jiroveci pneumonia

trimethoprim 160 mg + sulfamethoxazole 800 mg tablet, 10

10784N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*17.76	18.93	[a] Bactrim DS [RO]	[a] Resprim Forte [AF]
			[B]10.17	*27.93	18.93	[a] Septrin Forte [RW]	

MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

Macrolides

▪ AZITHROMYCIN

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit
Trachoma

azithromycin 200 mg/5 mL oral liquid: powder for, 15 mL

8201P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	..	..	#25.51	27.04	Zithromax [PF]

azithromycin 500 mg tablet, 2

8336R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	15.30	16.47	[a] APO-Azithromycin [TX] [a] Azithromycin Sandoz [SZ] [a] Terry White Chemists Azithromycin [TW]	[a] Azithromycin-GA [EA] [a] Chem mart Azithromycin [CH] [a] Zithromax [PF]

▪ AZITHROMYCIN

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit
Urethritis
Clinical criteria:
The condition must be uncomplicated and due to Chlamydia trachomatis.

Restricted benefit
Cervicitis
Clinical criteria:
The condition must be uncomplicated and due to Chlamydia trachomatis.

azithromycin 500 mg tablet, 2

8200N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	15.30	16.47	[a] APO-Azithromycin [TX] [a] Azithromycin Sandoz [SZ] [a] Terry White Chemists Azithromycin [TW]	[a] Azithromycin-GA [EA] [a] Chem mart Azithromycin [CH] [a] Zithromax [PF]

▪ CLARITHROMYCIN

clarithromycin 250 mg tablet, 14

8318T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	13.08	14.25	[a] APO-Clarithromycin [TX] [a] Clarac [ED] [a] Clarithro 250 [RW] [a] Clarithromycin Sandoz [SZ] [a] Terry White Chemists Clarithromycin [TW]	[a] Chem mart Clarithromycin [CH] [a] Clarihexal [HX] [a] Clarithromycin AN [EA] [a] Kalixocin [AF]
			[B]3.50	16.58	14.25	[a] Klacid [GO]	

▪ CLARITHROMYCIN

Restricted benefit
Bordetella pertussis

Restricted benefit
Atypical mycobacterial infections

clarithromycin 250 mg/5 mL oral liquid: powder for, 50 mL

9192T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	..	..	#29.18	30.71	Klacid [GO]

▪ ERYTHROMYCIN

erythromycin 250 mg capsule: enteric, 25

1404X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	1	..	15.20	16.37	[a] Mayne Pharma Erythromycin [YT]
			[B]2.53	17.73	16.37	[a] Eryc [YN]

erythromycin 250 mg capsule: enteric, 25

3325B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	15.20	16.37	[a] Mayne Pharma Erythromycin [YT]
			[B]2.53	17.73	16.37	[a] Eryc [YN]

▪ ERYTHROMYCIN

Authority required (STREAMLINED)

6160

Severe acne

Clinical criteria:

The condition must be one in which tetracycline therapy is inappropriate.

erythromycin 250 mg capsule: enteric, 25

10780J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*19.99	21.16	[a] Mayne Pharma Erythromycin [YT]
			[B]5.06	*25.05	21.16	[a] Eryc [YN]

▪ ERYTHROMYCIN ETHYLSUCCINATE

erythromycin (as ethylsuccinate) 200 mg/5 mL oral liquid: powder for, 100 mL

2424N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	1	..	#17.87	19.40	[a] E-Mycin 200 [AF]
			[B]2.36	#20.23	19.40	[a] E.E.S. 200 [ZC]

erythromycin (as ethylsuccinate) 200 mg/5 mL oral liquid: powder for, 100 mL

3334L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	‡1	..	..	#17.87	19.40	[a] E-Mycin 200 [AF]
			[B]2.36	#20.23	19.40	[a] E.E.S. 200 [ZC]

erythromycin (as ethylsuccinate) 400 mg tablet, 25

2750R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	1	..	15.32	16.49	[a] E-Mycin [AF]
			[B]2.33	17.65	16.49	[a] E.E.S. 400 Filmtab [ZC]

erythromycin (as ethylsuccinate) 400 mg tablet, 25

3336N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	15.32	16.49	[a] E-Mycin [AF]
			[B]2.33	17.65	16.49	[a] E.E.S. 400 Filmtab [ZC]

erythromycin (as ethylsuccinate) 400 mg/5 mL oral liquid: powder for, 100 mL

2428T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	1	..	#19.18	20.71	[a] E-Mycin 400 [AF]
			[B]2.38	#21.56	20.71	[a] E.E.S. Granules [ZC]

erythromycin (as ethylsuccinate) 400 mg/5 mL oral liquid: powder for, 100 mL

3337P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	‡1	..	..	#19.18	20.71	[a] E-Mycin 400 [AF]
			[B]2.38	#21.56	20.71	[a] E.E.S. Granules [ZC]

▪ ERYTHROMYCIN ETHYLSUCCINATE

Authority required (STREAMLINED)

6160

Severe acne

Clinical criteria:

The condition must be one in which tetracycline therapy is inappropriate.

erythromycin (as ethylsuccinate) 400 mg tablet, 25

10789W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*20.23	21.40	[a] E-Mycin [AF]

			[B]4.66	*24.89	21.40	[a] E.E.S. 400 Filmtab [ZC]

▪ ERYTHROMYCIN LACTOBIONATE

erythromycin (as lactobionate) 1 g injection, 1 vial

1397M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	5	..	..	*183.18	38.30	Erythrocin-I.V. [ZC]

erythromycin (as lactobionate) 1 g injection, 1 vial

5088T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	5	..	..	*183.18	38.30	Erythrocin-I.V. [ZC]

▪ ROXITHROMYCIN

roxithromycin 150 mg tablet, 10

1760P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	12.10	13.27	[a] APO-Roxithromycin [TX]	[a] Biaxsig [AV]
						[a] Chem mart Roxithromycin [CH]	[a] Roxar 150 [RW]
						[a] Roximycin [AF]	[a] Roxithromycin AN [EA]
						[a] Roxithromycin-GA [ED]	[a] Roxithromycin GH [GQ]
						[a] Roxithromycin Sandoz [SZ]	[a] Roxithromycin SCP 150 [CR]
						[a] Terry White Chemists Roxithromycin [TW]	
			[B]1.62	13.72	13.27	[a] Rulide [SW]	

roxithromycin 150 mg tablet, 10

5260W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	12.10	13.27	[a] APO-Roxithromycin [TX]	[a] Biaxsig [AV]
						[a] Chem mart Roxithromycin [CH]	[a] Roxar 150 [RW]
						[a] Roximycin [AF]	[a] Roxithromycin AN [EA]
						[a] Roxithromycin-GA [ED]	[a] Roxithromycin GH [GQ]
						[a] Roxithromycin Sandoz [SZ]	[a] Roxithromycin SCP 150 [CR]
						[a] Terry White Chemists Roxithromycin [TW]	
			[B]1.62	13.72	13.27	[a] Rulide [SW]	

roxithromycin 300 mg tablet, 5

5261X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	12.10	13.27	[a] APO-Roxithromycin [TX]	[a] Biaxsig [AV]
						[a] Chem mart Roxithromycin [CH]	[a] Roxar 300 [RW]
						[a] Roximycin [AF]	[a] Roxithromycin AN [EA]
						[a] Roxithromycin-GA [ED]	[a] Roxithromycin GH [GQ]
						[a] Roxithromycin Sandoz [SZ]	[a] Roxithromycin SCP 300 [CR]
						[a] Terry White Chemists Roxithromycin [TW]	
			[B]1.62	13.72	13.27	[a] Rulide [SW]	

roxithromycin 300 mg tablet, 5

8016X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	12.10	13.27	[a] APO-Roxithromycin [TX]	[a] Biaxsig [AV]
						[a] Chem mart Roxithromycin [CH]	[a] Roxar 300 [RW]
						[a] Roximycin [AF]	[a] Roxithromycin AN [EA]
						[a] Roxithromycin-GA [ED]	[a] Roxithromycin GH [GQ]
						[a] Roxithromycin Sandoz [SZ]	[a] Roxithromycin SCP 300 [CR]
						[a] Terry White Chemists Roxithromycin [TW]	
			[B]1.62	13.72	13.27	[a] Rulide [SW]	

roxithromycin 50 mg tablet: dispersible, 10

5259T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	16.05	17.22	Rulide D [SW]

roxithromycin 50 mg tablet: dispersible, 10

8129W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	1	..	16.05	17.22	Rulide D [SW]

Lincosamides

▪ CLINDAMYCIN

Restricted benefit
Gram-positive coccal infections
Clinical criteria:
The condition must not be able to be safely and effectively treated with a penicillin.

clindamycin 150 mg capsule, 24

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5057E DP	1	..	..	18.88	20.05	[a] APO-Clindamycin [TX] [a] Chem mart Clindamycin [CH] [a] Clindamycin BNM [BZ] [a] Clindamyk [AF]	[a] Calindamin [RW] [a] Cleocin [FZ] [a] Clindamycin-Link [LM] [a] Terry White Chemists Clindamycin [TW]
			[B]7.10	25.98	20.05	[a] Dalacin C [PF]	

▪ CLINDAMYCIN

Restricted benefit
Gram-positive coccal infections
Clinical criteria:
The condition must not be able to be safely and effectively treated with a penicillin.

clindamycin 150 mg capsule, 24

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3138E NP MW	2	1	..	*27.35	28.52	[a] APO-Clindamycin [TX] [a] Chem mart Clindamycin [CH] [a] Clindamycin BNM [BZ] [a] Clindamyk [AF]	[a] Calindamin [RW] [a] Cleocin [FZ] [a] Clindamycin-Link [LM] [a] Terry White Chemists Clindamycin [TW]
			[B]14.20	*41.55	28.52	[a] Dalacin C [PF]	

▪ LINCOMYCIN

lincomycin 600 mg/2 mL injection, 5 x 2 mL vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2530E NP MW	1	..	..	142.19	38.30	Lincocin [PF]

lincomycin 600 mg/2 mL injection, 5 x 2 mL vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5144R DP	1	..	..	142.19	38.30	Lincocin [PF]

AMINOGLYCOSIDE ANTIBACTERIALS

Other aminoglycosides

▪ GENTAMICIN

gentamicin 80 mg/2 mL injection, 10 x 2 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2824P NP	1	1	..	21.94	23.11	Pfizer Australia Pty Ltd [PF]

▪ TOBRAMYCIN

Restricted benefit
Pseudomonas aeruginosa infection
Clinical criteria:
Patient must have cystic fibrosis, AND
The treatment must be systemic.

tobramycin 500 mg/5 mL injection, 10 x 5 mL vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9480Y NP	1	1	..	331.49	38.30	Tobra-Day [PL]

▪ TOBRAMYCIN

Restricted benefit
Infection where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent
Restricted benefit
Septicaemia, suspected
Restricted benefit

Septicaemia, proven

tobramycin 80 mg/2 mL injection, 5 x 2 mL vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1356J NP	2	1	..	*61.05	38.30	Hospira Pty Limited [HH]

tobramycin Injection 80 mg (base) in 2 mL (without preservative), 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8872Y NP	2	1	..	*61.05	38.30	Pfizer Australia Pty Ltd [PF]

▪ TOBRAMYCIN

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

4456

Proven Pseudomonas aeruginosa infection

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have cystic fibrosis, AND

Patient must have been assessed for bronchial hyperresponsiveness as per the TGA-approved Product Information, with a negative test result, AND

Patient must be participating in a four week trial of tobramycin inhalation powder and will be assessed for ability to tolerate the dry powder formulation in order to qualify for continued PBS-subsidised therapy. The trial commencement date must be documented in the patient's medical records.

Population criteria:

Patient must be 6 years of age or older.

tobramycin 28 mg inhalation, 224 capsules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10066T	1	..	..	2429.72	38.30	TOBI podhaler [NV]

▪ TOBRAMYCIN

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

4513

Proven Pseudomonas aeruginosa infection

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have cystic fibrosis, AND

Patient must have previously been issued with an authority prescription for tobramycin inhalation capsules, AND

Patient must have demonstrated ability to tolerate the dry powder formulation following the initial 4-week treatment period, as agreed by the patient, the patient's family (in the case of paediatric patients) and the treating physician(s).

Population criteria:

Patient must be 6 years of age or older.

tobramycin 28 mg inhalation, 224 capsules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10074F	1	2	..	2429.72	38.30	TOBI podhaler [NV]

▪ TOBRAMYCIN

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

5520

Proven Pseudomonas aeruginosa infection

Clinical criteria:

Patient must have cystic fibrosis, AND

The treatment must be for management.

tobramycin 300 mg/5 mL inhalation: solution, 56 x 5 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5442K	1	2	..	2034.16	38.30	Tobi [NV]

QUINOLONE ANTIBACTERIALS

Fluoroquinolones

▪ CIPROFLOXACIN

Authority required

Respiratory tract infection

Clinical criteria:

The condition must be proven or suspected to be caused by Pseudomonas aeruginosa, AND

Patient must be severely immunocompromised.

Authority required

Bacterial gastroenteritis

Clinical criteria:

Patient must be severely immunocompromised.

Authority required

Infection

Clinical criteria:

The condition must be proven to be due to Pseudomonas aeruginosa resistant to all other oral antimicrobials; OR

The condition must be proven to be due to other gram-negative bacteria resistant to all other oral antimicrobials.

Authority required

Bone or joint infection

Clinical criteria:

The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR

The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Epididymo-orchitis

Clinical criteria:

The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR

The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Prostatitis

Clinical criteria:

The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR

The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Perichondritis of the pinna

Clinical criteria:

The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR

The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

ciprofloxacin 500 mg tablet, 14

1209P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	17.98	19.15	[a] APO-Ciprofloxacin [TX] [a] Cifran [RA] [a] Ciprofloxacin AN [EA] [a] Ciprofloxacin-GA [ED] [a] Ciprol 500 [RW] [a] Loxip 500 [DO]	[a] C-Flox 500 [AL] [a] Ciprofloxacin 500 [CR] [a] Ciprofloxacin-BW [GQ] [a] Ciprofloxacin Sandoz [SZ] [a] GenRx Ciprofloxacin [GX]
		[B]2.93	20.91	19.15	[a] Ciproxin 500 [BN]	

ciprofloxacin 750 mg tablet, 14

1210Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	21.82	22.99	[a] APO-Ciprofloxacin [TX] [a] Cifran [RA] [a] Ciprofloxacin AN [EA] [a] Ciprofloxacin-GA [ED] [a] Ciprol 750 [RW] [a] Loxip 750 [DO]	[a] C-Flox 750 [AL] [a] Ciprofloxacin 750 [CR] [a] Ciprofloxacin-BW [GQ] [a] Ciprofloxacin Sandoz [SZ] [a] GenRx Ciprofloxacin [GX]

▪ CIPROFLOXACIN

Authority required

Respiratory tract infection

Clinical criteria:

The condition must be proven or suspected to be caused by Pseudomonas aeruginosa, AND

Patient must be severely immunocompromised.

Authority required

Bacterial gastroenteritis

Clinical criteria:

Patient must be severely immunocompromised.

Authority required

Infection

Clinical criteria:

The condition must be proven to be due to Pseudomonas aeruginosa resistant to all other oral antimicrobials; OR

The condition must be proven to be due to other gram-negative bacteria resistant to all other oral antimicrobials.

Authority required

Bone or joint infection

Clinical criteria:

The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR

The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Epididymo-orchitis

Clinical criteria:

The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR

The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Prostatitis

Clinical criteria:

The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR

The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Perichondritis of the pinna

Clinical criteria:

The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR

The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Gonorrhoea

ciprofloxacin 250 mg tablet, 14

1208N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	14.29	15.46	[a] APO-Ciprofloxacin [TX] [a] Ciprofloxacin Sandoz [SZ] [a] GenRx Ciprofloxacin [GX]	[a] C-Flox 250 [AL] [a] Ciprol 250 [RW]
			[B]2.10	16.39	15.46	[a] Ciproxin 250 [BN]	

▪ NORFLOXACIN

Authority required

Acute bacterial enterocolitis

Authority required

Complicated urinary tract infection

norfloxacin 400 mg tablet, 14

3010K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	14.44	15.61	[a] GenRx Norfloxacin [GX] [a] Nufloxib [AF]	[a] Norfloxacin Sandoz [SZ] [a] Roxin [RW]

OTHER ANTIBACTERIALS

Glycopeptide antibacterials

▪ VANCOMYCIN

Restricted benefit
Endocarditis
Clinical criteria:
The treatment must be for prophylaxis, AND
Patient must be hypersensitive to penicillin.

vancomycin 1 g injection, 1 vial

2269K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	13.52	14.69	[a] Hospira Pty Limited [HH] [a] Vancomycin Sandoz [SZ]	[a] Vancomycin Alphapharm [AF] [a] Vycin IV [EA]

vancomycin 500 mg injection, 1 vial

3130R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*13.51	14.68	[a] Hospira Pty Limited [HH] [a] Vancomycin Alphapharm [AF]	[a] Vancocin CP [AS] [a] Vancomycin Sandoz [SZ]

▪ VANCOMYCIN

Restricted benefit
Endocarditis
Clinical criteria:
The treatment must be for prophylaxis, AND
Patient must be hypersensitive to penicillin.

vancomycin 1 g injection, 1 vial

5083M DP	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	13.52	14.69	[a] Hospira Pty Limited [HH] [a] Vancomycin Sandoz [SZ]	[a] Vancomycin Alphapharm [AF] [a] Vycin IV [EA]

vancomycin 500 mg injection, 1 vial

3323X DP	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*13.51	14.68	[a] Hospira Pty Limited [HH] [a] Vancomycin Alphapharm [AF]	[a] Vancocin CP [AS] [a] Vancomycin Sandoz [SZ]

▪ VANCOMYCIN

Restricted benefit
Endophthalmitis
Restricted benefit
Infection
Clinical criteria:
The treatment must be initiated in a hospital, AND
The condition must be one in which vancomycin is an appropriate antibiotic.

vancomycin 1 g injection, 1 vial

2270L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*19.71	20.88	[a] Hospira Pty Limited [HH] [a] Vancomycin Sandoz [SZ]	[a] Vancomycin Alphapharm [AF] [a] Vycin IV [EA]

vancomycin 500 mg injection, 1 vial

3131T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	..	..	*18.13	19.30	[a] Hospira Pty Limited [HH] [a] Vancomycin Alphapharm [AF]	[a] Vancocin CP [AS] [a] Vancomycin Sandoz [SZ]

Steroid antibacterials

▪ FUSIDATE

Restricted benefit
Serious staphylococcal infections
Clinical criteria:
The treatment must be used in combination with another antibiotic, AND
The condition must be proven to be due to a staphylococcus.

fusidate sodium 250 mg tablet, 36

2312Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	83.37	38.30	Fucidin [CS]

▪ FUSIDATE

Authority required (STREAMLINED)
6133

Osteomyelitis
Clinical criteria:
The condition must be methicillin-resistant staphylococcal aureus (MRSA), AND
The treatment must be used in combination with other anti-staphylococcal antibiotics.

fusidate sodium 250 mg tablet, 36

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10782L	2	1	..	*156.33	38.30	Fucidin [CS]

Imidazole derivatives

▪ METRONIDAZOLE

metronidazole 200 mg tablet, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1636D NP	1	1	..	11.69	12.86	[a] Metrogyl 200 [AF]	[a] Metronide 200 [AV]
			[B]2.00	13.69	12.86	[a] Flagyl [SW]	

metronidazole 200 mg tablet, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3339R DP	1	..	..	11.69	12.86	[a] Metrogyl 200 [AF]	[a] Metronide 200 [AV]
			[B]2.00	13.69	12.86	[a] Flagyl [SW]	

metronidazole 200 mg/5 mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1630T NP	‡1	..	..	21.20	22.37	Flagyl S [SW]

metronidazole 200 mg/5 mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3341W DP	‡1	..	..	21.20	22.37	Flagyl S [SW]

metronidazole 500 mg suppository, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1642K NP	‡1	..	..	24.98	26.15	Flagyl [SW]

metronidazole 500 mg suppository, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5157K DP	‡1	..	..	24.98	26.15	Flagyl [SW]

▪ METRONIDAZOLE

Restricted benefit
Anaerobic infections

metronidazole 400 mg tablet, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1621H NP	1	1	..	13.40	14.57	[a] Metrogyl 400 [AF]	[a] Metronide 400 [AV]
			[B]2.00	15.40	14.57	[a] Flagyl [SW]	

▪ METRONIDAZOLE

Restricted benefit
Anaerobic infections

metronidazole 400 mg tablet, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5155H DP	1	..	..	13.40	14.57	[a] Metrogyl 400 [AF]	[a] Metronide 400 [AV]
			[B]2.00	15.40	14.57	[a] Flagyl [SW]	

▪ METRONIDAZOLE

Note Pharmaceutical benefits that have the form metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags and pharmaceutical benefits that have the form metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags are equivalent for the purposes of substitution.

Restricted benefit
Acute anaerobic sepsis
Treatment criteria:
Must be treated in a hospital.

metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1832K DP	1	..	..	20.14	21.31	[a] DBL Metronidazole Intravenous Infusion [HH]	[a] Metronidazole Sandoz IV [SZ]

metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2298Y DP	2	..	..	*20.15	21.32	[a] Metronidazole-Claris [AE]

▪ METRONIDAZOLE

Note Pharmaceutical benefits that have the form metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags and pharmaceutical benefits that have the form metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags are equivalent for the purposes of substitution.

Restricted benefit

Prophylaxis to prevent infection

Clinical criteria:

Patient must be undergoing large bowel surgery.

Restricted benefit

Acute anaerobic sepsis

Treatment criteria:

Must be treated in a hospital.

metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1821W NP	1	..	..	20.14	21.31	[a] DBL Metronidazole Intravenous Infusion [HH]	[a] Metronidazole Sandoz IV [SZ]

metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2277W NP	2	..	..	*20.15	21.32	[a] Metronidazole-Claris [AE]

▪ TINIDAZOLE

tinidazole 500 mg tablet, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1465D NP	1	..	..	14.22	15.39	[a] Simplotan [FZ]
			[B]4.70	18.92	15.39	[a] Fasigyn [PF]

Nitrofuran derivatives

▪ NITROFURANTOIN

Caution Nitrofurantoin may cause peripheral neuritis and severe pulmonary reactions.

nitrofurantoin 100 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1693D NP MW	1	1	..	30.40	31.57	Macrodantin [PF]

nitrofurantoin 50 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1692C NP MW	1	1	..	24.66	25.83	Macrodantin [PF]

Other antibacterials

▪ HEXAMINE HIPPURATE

hexamine hippurate 1 g tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3124K NP	1	5	..	43.44	38.30	Hiprex [IA]

▪ ANTIMYCOTICS FOR SYSTEMIC USE

ANTIMYCOTICS FOR SYSTEMIC USE

Triazole derivatives

▪ FLUCONAZOLE

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

Restricted benefit

Cryptococcal meningitis
Restricted benefit
Cryptococcal meningitis
Clinical criteria:
The treatment must be maintenance therapy, AND
Patient must be immunosuppressed.
Restricted benefit
Oropharyngeal candidiasis
Clinical criteria:
Patient must be immunosuppressed.
Restricted benefit
Oesophageal candidiasis
Clinical criteria:
Patient must be immunosuppressed.
Restricted benefit
Oropharyngeal candidiasis
Clinical criteria:
The treatment must be for prophylaxis, AND
Patient must be immunosuppressed.
Restricted benefit
Candida infections
Clinical criteria:
The condition must be serious or life-threatening.

fluconazole 100 mg capsule, 28

1472L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	38.70	38.30	[a] Diflucan [PF] [a] Fluconazole Sandoz [SZ]	[a] Dizole 100 [AF] [a] Ozole [RA]

fluconazole 100 mg/50 mL injection, 50 mL vial

1473M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	7	..	..	*21.63	22.80	[a] Fluconazole Hexal [HX]	[a] Fluconazole Sandoz [SZ]

fluconazole 200 mg capsule, 28

1475P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	65.50	38.30	[a] APO-Fluconazole [TX] [a] Dizole 200 [AF] [a] Fluzole 200 [RW]	[a] Diflucan [PF] [a] Fluconazole Sandoz [SZ] [a] Ozole [RA]

fluconazole 200 mg/100 mL injection, 100 mL vial

1474N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	7	..	..	*31.57	32.74	[a] Fluconazole Alphapharm [AF] [a] Fluconazole Sandoz [SZ]	[a] Fluconazole Hexal [HX]

fluconazole 400 mg/200 mL injection, 200 mL bag

1757L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	15.17	16.34	Fluconazole Alphapharm [AF]

fluconazole 50 mg capsule, 28

1471K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	24.95	26.12	[a] Diflucan [PF] [a] Fluconazole Sandoz [SZ]	[a] Dizole 50 [AF] [a] Ozole [RA]

▪ FLUCONAZOLE

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

Restricted benefit
Cryptococcal meningitis
Clinical criteria:
Patient must be unable to take a solid dose form of fluconazole.
Restricted benefit
Cryptococcal meningitis
Clinical criteria:
The treatment must be maintenance therapy, AND
Patient must be immunosuppressed, AND

Patient must be unable to take a solid dose form of fluconazole.

Restricted benefit

Oropharyngeal candidiasis

Clinical criteria:

Patient must be immunosuppressed, AND

Patient must be unable to take a solid dose form of fluconazole.

Restricted benefit

Oesophageal candidiasis

Clinical criteria:

Patient must be immunosuppressed, AND

Patient must be unable to take a solid dose form of fluconazole.

Restricted benefit

Oropharyngeal candidiasis

Clinical criteria:

The treatment must be for prophylaxis, AND

Patient must be immunosuppressed, AND

Patient must be unable to take a solid dose form of fluconazole.

Restricted benefit

Candida infections

Clinical criteria:

The condition must be serious or life-threatening, AND

Patient must be unable to take a solid dose form of fluconazole.

fluconazole 50 mg/5 mL oral liquid: powder for, 35 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5446P NP	1	..	..	#66.61	38.30	Diflucan [PF]

▪ ITRACONAZOLE

Note One capsule of itraconazole 50 mg (Lozanoc) is therapeutically equivalent to one 100 mg capsule of conventional itraconazole (Sporanox). The recommended dose of Lozanoc is therefore half the recommended dose for Sporanox. Lozanoc 50 mg capsules and Sporanox 100 mg capsules are not interchangeable.

Note Not for use in superficial mycoses

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

Restricted benefit

Systemic aspergillosis

Restricted benefit

Systemic sporotrichosis

Restricted benefit

Systemic histoplasmosis

Restricted benefit

Disseminated pulmonary histoplasmosis infection

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS).

Restricted benefit

Chronic pulmonary histoplasmosis infection

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

Patient must be diagnosed with acquired immunodeficiency syndrome (AIDS).

Restricted benefit

Oropharyngeal candidiasis

Clinical criteria:

Patient must be immunosuppressed.

Restricted benefit

Oesophageal candidiasis

Clinical criteria:

Patient must be immunosuppressed.

itraconazole 100 mg capsule, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8196J NP	1	5	..	222.77	38.30	Sporanox [JC]

itraconazole 50 mg capsule, 60

10732W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	150.39	38.30	Lozanoc [YN]

▪ POSACONAZOLE

Note Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

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

Authority required

Invasive aspergillosis

Clinical criteria:

Patient must be unable to tolerate alternative therapy; OR

Patient must have disease refractory to alternative therapy.

Authority required

Prophylaxis of invasive fungal infections including both yeasts and moulds

Clinical criteria:

Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre), for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR

Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or extensive chronic GVHD, and receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant.

Treatment of neutropenia should continue until recovery of the neutrophil count to at least 500 cells per cubic millimetre.

Patients who have had a previous invasive fungal infection should have secondary prophylaxis during subsequent episodes of neutropenia.

No more than 6 months therapy per episode will be PBS-subsidised

Authority required

Fungal infection

Clinical criteria:

The condition must be fusariosis; OR

The condition must be zygomycosis; OR

The condition must be coccidioidomycosis; OR

The condition must be chromoblastomycosis; OR

The condition must be mycetoma, AND

Patient must be unable to tolerate alternative therapy; OR

Patient must have disease refractory to alternative therapy.

posaconazole 100 mg tablet: modified release, 24

10460M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	833.98	38.30	Noxafil [MK]

▪ POSACONAZOLE

Note Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

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

Authority required

Invasive aspergillosis

Clinical criteria:

Patient must be unable to tolerate alternative therapy; OR

Patient must have disease refractory to alternative therapy.

Authority required

Fungal infection

Clinical criteria:

The condition must be fusariosis; OR

The condition must be zygomycosis; OR

The condition must be coccidioidomycosis; OR

The condition must be chromoblastomycosis; OR

The condition must be mycetoma, AND

Patient must be unable to tolerate alternative therapy; OR

Patient must have disease refractory to alternative therapy.

Authority required

Prophylaxis of invasive fungal infections including both yeasts and moulds

Clinical criteria:

Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre), for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR

Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or extensive chronic GVHD, and receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant.

No more than 6 months therapy per episode will be PBS-subsidised

posaconazole 40 mg/mL oral liquid, 105 mL

9360P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	691.30	38.30	Noxafil [MK]

▪ VORICONAZOLE

Note For patients with graft versus host disease, acute myeloid leukaemia or myelodysplastic syndrome, applications for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

Note For patients undergoing allogeneic haematopoietic stem cell transplant, applications for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 2 months' treatment may be authorised.

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

Authority required

Prophylaxis of invasive fungal infections including both yeasts and moulds

Clinical criteria:

Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre) for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR

Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or, extensive chronic GVHD, whilst receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant; OR

Patient must be undergoing allogeneic haematopoietic stem cell transplant using either bone marrow from an unrelated donor or umbilical cord blood (related or unrelated), and, be considered to be at high risk of developing an invasive fungal infection during the neutropenic phase prior to engraftment.

voriconazole 200 mg tablet, 56

10198R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	1894.56	38.30	[a] Vfend [PF] [a] Vttack [AF]	[a] Voriconazole Sandoz [SZ]

voriconazole 40 mg/mL oral liquid: powder for, 70 mL

10168E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	#495.46	38.30	Vfend [PF]

voriconazole 50 mg tablet, 56

10173K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	492.81	38.30	[a] Vfend [PF] [a] Vttack [AF]	[a] Voriconazole Sandoz [SZ]

▪ VORICONAZOLE

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

Authority required

Definite or probable invasive aspergillosis

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

Patient must be immunocompromised.

Authority required

Serious fungal infections

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

The condition must be caused by Scedosporium species; OR

The condition must caused by Fusarium species.

Authority required
Serious Candida infections
Treatment Phase: Treatment and maintenance therapy
Clinical criteria:
The condition must be caused by species not susceptible to fluconazole; OR
The condition must be resistant to fluconazole; OR
Patient must be unable to tolerate fluconazole.
Authority required
Serious invasive mycosis infections
Treatment Phase: Treatment and maintenance therapy
Clinical criteria:
The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.

voriconazole 200 mg tablet, 56

9364W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	1894.56	38.30	[a] Vfend [PF] [a] Vttack [AF]	[a] Voriconazole Sandoz [SZ]

voriconazole 50 mg tablet, 56

9363T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	492.81	38.30	[a] Vfend [PF] [a] Vttack [AF]	[a] Voriconazole Sandoz [SZ]

▪ VORICONAZOLE

Note Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

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

Authority required
Definite or probable invasive aspergillosis
Treatment Phase: Treatment and maintenance therapy
Clinical criteria:
Patient must be immunocompromised.
Authority required
Serious fungal infections
Treatment Phase: Treatment and maintenance therapy
Clinical criteria:
The condition must be caused by Scedosporium species; OR
The condition must caused by Fusarium species.
Authority required
Serious Candida infections
Treatment Phase: Treatment and maintenance therapy
Clinical criteria:
The condition must be caused by species not susceptible to fluconazole; OR
The condition must be resistant to fluconazole; OR
Patient must be unable to tolerate fluconazole.
Authority required
Serious invasive mycosis infections
Treatment Phase: Treatment and maintenance therapy
Clinical criteria:
The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.

voriconazole 40 mg/mL oral liquid: powder for, 70 mL

9452L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	#495.46	38.30	Vfend [PF]

▪ ANTIMYCOBACTERIALS

DRUGS FOR TREATMENT OF TUBERCULOSIS

Hydrazides

▪ ISONIAZID

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

isoniazid 100 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1554T NP	1	2	..	22.86	24.03	Arrow Pharma Pty Ltd [RW]

DRUGS FOR TREATMENT OF LEPRA

Drugs for treatment of lepra

▪ DAPSONE

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

dapsone 100 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1272Y NP	1	1	..	103.19	38.30	Link Medical Products Pty Ltd [LM]

dapsone 25 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8801F NP	1	1	..	91.74	38.30	Link Medical Products Pty Ltd [LM]

▪ RIFAMPICIN

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

Authority required
Leprosy
Population criteria:
Patient must be an adult.

rifampicin 150 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1982H NP	1	..	..	280.77	38.30	Rimycin 150 [AF]

rifampicin 300 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1983J NP	1	..	..	132.35	38.30	Rimycin 300 [AF]

▪ RIFAMPICIN

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

Restricted benefit
Meningococcal disease
Clinical criteria:
The treatment must be for prophylaxis, AND
Patient must be a carrier of the disease; OR
Patient must be in close contact with people who have the disease.
Restricted benefit
Haemophilus influenzae type B
Clinical criteria:
The treatment must be for prophylaxis, AND
Patient must be in contact with people who have the disease.

rifampicin 100 mg/5 mL oral liquid, 60 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8025J NP	‡1	..	..	30.18	31.35	Rifadin [SW]

rifampicin 150 mg capsule, 10

1981G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	37.15	38.30	Rimycin 150 [AF]

rifampicin 300 mg capsule, 10

1984K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	22.61	23.78	Rimycin 300 [AF]

ANTIVIRALS FOR SYSTEMIC USE

DIRECT ACTING ANTIVIRALS

Nucleosides and nucleotides excl. reverse transcriptase inhibitors

ACICLOVIR

Authority required (STREAMLINED)

5946

Advanced human immunodeficiency virus (HIV) disease

Clinical criteria:

Patient must have CD4 cell counts of less than 150 million per litre.

aciclovir 800 mg tablet, 120

8234J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	143.68	38.30	Acyclo-V 800 [AF]

ACICLOVIR

Note Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

Authority required (STREAMLINED)

5942

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment or suppressive therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

aciclovir 200 mg tablet, 90

1007B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	42.55	38.30	[a] Aciclovir 200 [CR] [a] Aciclovir Sandoz [HX] [a] Chem mart Aciclovir [CH] [a] Lovir [GN] [a] Terry White Chemists Aciclovir [TW]	[a] Aciclovir GH [GQ] [a] Acyclo-V 200 [AF] [a] GenRx Aciclovir [GX] [a] Ozvir [RA]
			[B]1.19	43.74	38.30	[a] Zovirax 200 mg [GK]	

ACICLOVIR

Note This drug is only effective if commenced within 72 hours of onset of rash.

Note Aciclovir 800 mg is not PBS-subsidised for herpes simplex or chickenpox.

Note No applications for repeats will be authorised.

Authority required (STREAMLINED)

5967

Herpes zoster

Clinical criteria:

The treatment must be administered within 72 hours of the onset of the rash.

Authority required (STREAMLINED)

5959

Herpes zoster ophthalmicus

aciclovir 800 mg tablet, 35

1052J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	49.29	38.30	[a] Aciclovir 800 [CR] [a] Acyclo-V 800 [AF]	[a] Aciclovir Sandoz [HX] [a] GenRx Aciclovir [GX]
			[B]0.59	49.88	38.30	[a] Zovirax 800 mg [GK]	

ACICLOVIR

Note Aciclovir 200 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note For item codes 1003T and 1555W, pharmaceutical benefits that have the form tablet 200 mg are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

5936

Initial moderate to severe genital herpes

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

aciclovir 200 mg tablet, 25

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1003T NP	2	..	..	*28.27	29.44	[a] Aciclovir Sandoz [HX] [a] Lovir [GN]	[a] Acyclo-V 200 [AF]
			[B]1.42	*29.69	29.44	[a] Zovirax 200 mg [GK]	

aciclovir 200 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1555W NP	1	..	..	28.27	29.44	[a] GenRx Aciclovir [GX]

▪ FAMCICLOVIR

Note Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

Authority required (STREAMLINED)

5971

Recurrent moderate to severe genital herpes

Treatment Phase: Suppressive therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

famciclovir 250 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8217L NP	1	5	..	104.87	38.30	[a] APO-Famciclovir [TX] [a] Ezovir [AF] [a] Famciclovir-GA [ED] [a] Famciclovir Sandoz [SZ] [a] Famlo [RA] [a] Favic 250 [RW]	[a] Auro-Famciclovir 250 [DO] [a] Famciclovir AN [EA] [a] Famciclovir generichealth 250 [GQ] [a] Famciclovir SCP 250 [CR] [a] Famvir [NV]

▪ FAMCICLOVIR

Note Famciclovir 125 mg is not PBS-subsidised for chickenpox, herpes zoster or herpes simplex infections other than genital herpes.

Note Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

Authority required (STREAMLINED)

5937

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

famciclovir 125 mg tablet, 40

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8092X NP	1	1	..	44.15	38.30	[a] APO-Famciclovir [TX] [a] Ezovir [AF] [a] Famciclovir-GA [ED] [a] Favic 125 [RW]	[a] Auro-Famciclovir 125 [DO] [a] Famciclovir AN [EA] [a] Famvir [NV]

famciclovir 250 mg tablet, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2274Q NP	1	1	..	44.15	38.30	[a] APO-Famciclovir [TX] [a] Famciclovir AN [EA] [a] Famciclovir Sandoz [SZ] [a] Favic 250 [RW]	[a] Ezovir [AF] [a] Famciclovir-GA [ED] [a] Famvir [NV]

▪ FAMCICLOVIR

Note This drug is only effective if commenced within 72 hours of onset of rash.

Note Famciclovir 250 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

Note No applications for repeats will be authorised.

Authority required (STREAMLINED)

5951

Herpes zoster

Clinical criteria:

The treatment must be administered within 72 hours of the onset of the rash.

famciclovir 250 mg tablet, 21

8002E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	45.84	38.30	[a] APO-Famciclovir [TX] [a] Ezovir [AF] [a] Famciclovir-GA [ED] [a] Famciclovir Sandoz [SZ] [a] Famlo [RA] [a] Favic 250 [RW]	[a] Auro-Famciclovir 250 [DO] [a] Famciclovir AN [EA] [a] Famciclovir generichealth 250 [GQ] [a] Famciclovir SCP 250 [CR] [a] Famvir [NV]

▪ FAMCICLOVIR

Note This drug is only effective if commenced within 72 hours of onset of rash.

Note Famciclovir 500 mg is not PBS-subsidised for chickenpox.

Note Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

Note No applications for repeats will be authorised.

Authority required (STREAMLINED)

5943

Herpes zoster

Clinical criteria:

Patient must be immunocompromised, AND

The treatment must be administered within 72 hours of the onset of the rash.

famciclovir 500 mg tablet, 30

8897G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	61.02	38.30	[a] APO-Famciclovir [TX] [a] Chem mart Famciclovir [CH] [a] Famciclovir Sandoz [SZ] [a] Favic 500 [RW]	[a] Auro-Famciclovir 500 [DO] [a] Famciclovir AN [EA] [a] Famvir [NV] [a] Terry White Chemists Famciclovir [TW]

▪ FAMCICLOVIR

Note Famciclovir 500 mg is not PBS-subsidised for chickenpox.

Note Famciclovir 500 mg is not PBS-subsidised for herpes zoster, genital herpes or other herpes simplex infections in immunocompetent patients.

Authority required (STREAMLINED)

5954

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment or suppressive therapy

Clinical criteria:

Patient must be immunocompromised.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

Authority required (STREAMLINED)

5947

Recurrent moderate to severe oral or labial herpes

Treatment Phase: Episodic treatment

Clinical criteria:

Patient must have HIV infection, AND

Patient must have a CD4 cell count of less than 500 million per litre.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

Authority required (STREAMLINED)

5948

Recurrent moderate to severe oral or labial herpes

Treatment Phase: Suppressive therapy

Clinical criteria:

Patient must have HIV infection, AND

Patient must have CD4 cell counts of less than 150 million per litre.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

Authority required (STREAMLINED)

5949

Recurrent moderate to severe oral or labial herpes

Treatment Phase: Suppressive therapy

Clinical criteria:

Patient must have HIV infection, AND

Patient must present with other opportunistic infections or AIDS defining tumours.

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

famciclovir 500 mg tablet, 56

8896F (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	104.88	38.30	[a] APO-Famciclovir [TX] [a] Chem mart Famciclovir [CH] [a] Famciclovir AN [EA] [a] Famciclovir generichealth 500 [GQ] [a] Famvir [NV] [a] Terry White Chemists Famciclovir [TW]	[a] Auro-Famciclovir 500 [DO] [a] Ezovir [AF] [a] Famciclovir-GA [ED] [a] Famciclovir Sandoz [SZ] [a] Favic 500 [RW]

▪ RIBAVIRIN

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 12 weeks.

Population criteria:

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

ribavirin 400 mg tablet, 28

10647J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	160.95	38.30	Ibavyr [IX]

ribavirin 600 mg tablet, 28

10665H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	237.81	38.30	Ibavyr [IX]

▪ RIBAVIRIN

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 24 weeks.

Population criteria:

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

ribavirin 400 mg tablet, 28

10673R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	160.95	38.30	Ibavyr [IX]

ribavirin 600 mg tablet, 28

10666J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	237.81	38.30	Ibavyr [IX]

▪ VALACICLOVIR

Note Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

Authority required (STREAMLINED)

5940

Recurrent moderate to severe genital herpes

Treatment Phase: Suppressive therapy

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

valaciclovir 500 mg tablet, 30

5480K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	37.52	38.30	[a] APO-Valaciclovir [TX]	[a] Chem mart Valaciclovir [CH]
					[a] Shilova 500 [DO]	[a] Terry White Chemists Valaciclovir [TW]
					[a] Vaclovir [AF]	[a] Valaciclovir Actavis [ED]
					[a] Valaciclovir AN [EA]	[a] Valaciclovir generichealth [GQ]
					[a] Valaciclovir RBX [RA]	[a] Valaciclovir SZ [HX]
					[a] Valacor 500 [CR]	[a] Valnir [OW]
					[a] Valtrex [RW]	[a] Zelitrex [RF]

▪ VALACICLOVIR

Note Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

Authority required (STREAMLINED)

5961

Recurrent moderate to severe genital herpes

Treatment Phase: Episodic treatment

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

valaciclovir 500 mg tablet, 30

8134D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	37.52	38.30	[a] APO-Valaciclovir [TX]	[a] Chem mart Valaciclovir [CH]
					[a] Shilova 500 [DO]	[a] Terry White Chemists Valaciclovir [TW]
					[a] Vaclovir [AF]	[a] Valaciclovir Actavis [ED]
					[a] Valaciclovir AN [EA]	[a] Valaciclovir generichealth [GQ]
					[a] Valaciclovir RBX [RA]	[a] Valaciclovir Sandoz [SZ]
					[a] Valaciclovir SZ [HX]	[a] Valacor 500 [CR]
					[a] Valnir [OW]	[a] Valtrex [RW]
					[a] Zelitrex [RF]	

▪ VALACICLOVIR

Note Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

5960

Initial moderate to severe genital herpes

Microbiological confirmation of diagnosis [viral culture, antigen detection or nucleic acid amplification by polymerase chain reaction (PCR)] is desirable but need not delay treatment.

valaciclovir 500 mg tablet, 10

8133C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	..	..	*28.49	29.66	[a] APO-Valaciclovir [TX]	[a] Vaclovir [AF]
					[a] Valaciclovir Actavis [ED]	[a] Valaciclovir AN [EA]
					[a] Valaciclovir Sandoz [SZ]	[a] Valnir [OW]
					[a] Valtrex [RW]	[a] Zelitrex [RF]

▪ VALACICLOVIR

Note This drug is only effective if commenced within 72 hours of onset of rash.

Note Valaciclovir 500 mg is not PBS-subsidised for chickenpox or herpes simplex infections other than genital herpes.

Note No applications for repeats will be authorised.

Authority required (STREAMLINED)

5962

Herpes zoster

Clinical criteria:

The treatment must be administered within 72 hours of the onset of the rash.

Authority required (STREAMLINED)

5968

Herpes zoster ophthalmicus

valaciclovir 500 mg tablet, 42

8064K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	48.35	38.30	[a] APO-Valaciclovir [TX] [a] Terry White Chemists Valaciclovir [TW] [a] Valaciclovir Actavis [ED] [a] Valaciclovir generichealth [GQ] [a] Valaciclovir Sandoz [SZ] [a] Valnir [OW] [a] Zelitrex [RF]	[a] Chem mart Valaciclovir [CH] [a] Vaclovir [AF] [a] Valaciclovir AN [EA] [a] Valaciclovir RBX [RA] [a] Valacor 500 [CR] [a] Valtrex [RW]

Other antivirals

▪ DACLATASVIR

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection
Clinical criteria:
Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
The treatment must be limited to a maximum duration of 12 weeks.

daclatasvir 30 mg tablet, 28

10645G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	7813.54	38.30	Daklinza [BQ]

daclatasvir 60 mg tablet, 28

10642D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	7813.54	38.30	Daklinza [BQ]

▪ DACLATASVIR

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection
Clinical criteria:
Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
The treatment must be limited to a maximum duration of 24 weeks.

daclatasvir 30 mg tablet, 28

10671P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	7813.54	38.30	Daklinza [BQ]

daclatasvir 60 mg tablet, 28

10659B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	7813.54	38.30	Daklinza [BQ]

▪ LEDIPASVIR + SOFOSBUVIR

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection
Clinical criteria:
Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
The treatment must be limited to a maximum duration of 12 weeks.

ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

10628J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	22213.54	38.30	Harvoni [GI]

▪ LEDIPASVIR + SOFOSBUVIR

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection
Clinical criteria:
Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
The treatment must be limited to a maximum duration of 8 weeks.

ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

10668L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	22213.54	38.30	Harvoni [GI]

▪ LEDIPASVIR + SOFOSBUVIR

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection
Clinical criteria:
Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
The treatment must be limited to a maximum duration of 24 weeks.

ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

10670N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	22213.54	38.30	Harvoni [GI]

▪ PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection
Clinical criteria:
Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
The treatment must be limited to a maximum duration of 12 weeks.

paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56], 4 x 28

10766P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	14000.00	38.30	Viekira Pak [VE]

▪ PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR & RIBAVIRIN

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection
Clinical criteria:
Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
The treatment must be limited to a maximum duration of 24 weeks.
Population criteria:

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 200 mg tablet [168], 1 pack

10771X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	14000.00	38.30	Viekira Pak-RBV [VE]

paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 600 mg tablet [56], 1 pack

10747P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	14000.00	38.30	Viekira Pak-RBV [VE]

▪ PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR & RIBAVIRIN

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 12 weeks.

Population criteria:

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 200 mg tablet [168], 1 pack

10772Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	14000.00	38.30	Viekira Pak-RBV [VE]

paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 600 mg tablet [56], 1 pack

10769T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	14000.00	38.30	Viekira Pak-RBV [VE]

▪ SOFOSBUVIR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 12 weeks.

sofosbuvir 400 mg tablet, 28

10624E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	19444.62	38.30	Sovaldi [GI]

▪ SOFOSBUVIR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 24 weeks.

sofosbuvir 400 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10657X	1	5	..	19444.62	38.30	Sovaldi [GI]

▪ VACCINES

BACTERIAL VACCINES

Pneumococcal vaccines

▪ PNEUMOCOCCAL PURIFIED CAPSULAR POLYSACCHARIDES

Restricted benefit
Prophylaxis of pneumococcal infection
Clinical criteria:
Patient must have undergone a splenectomy.
Population criteria:
Patient must be aged 2 years or older.
Restricted benefit
Prophylaxis of pneumococcal infection
Clinical criteria:
Patient must have Hodgkin's disease; OR
Patient must have a high risk of contracting pneumococcal infections.

pneumococcal purified capsular polysaccharides 25 microgram/0.5 mL injection, 0.5 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10210J NP	1	..	..	46.29	38.30	Pneumovax 23 [CS]

pneumococcal purified capsular polysaccharides 25 microgram/0.5 mL injection, 0.5 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1903E NP	1	..	..	46.29	38.30	Pneumovax 23 [CS]

Tetanus vaccines

▪ DIPHTHERIA TOXOID + TETANUS TOXOID

Note For immunisation of adults and children aged greater than or equal to 8 years.

diphtheria toxoid 2 Lf/0.5 mL + tetanus toxoid 2 Lf/0.5 mL injection, 10 x 0.5 mL vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10261C NP	1	..	..	129.46	38.30	MassBiologics tetanus and diphtheria toxoids adsorbed [CS]

diphtheria toxoid 2 international units/0.5 mL + tetanus toxoid 20 international units/0.5 mL injection, 5 x 0.5 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8783G NP	1	..	..	69.94	38.30	ADT Booster [CS]

▪ ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

▪ ANTINEOPLASTIC AGENTS

ALKYLATING AGENTS

Nitrogen mustard analogues

▪ CHLORAMBUCIL

chlorambucil 2 mg tablet, 25

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1163F	4	2	..	*137.69	38.30	Leukeran [AS]

▪ CYCLOPHOSPHAMIDE

cyclophosphamide 50 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10026Q	1	2	..	76.81	38.30	Endoxan [BX]

cyclophosphamide 50 mg tablet, 50

1266P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	30.97	32.14	Cycloblastin [ZX]

▪ MELPHALAN

melphalan 2 mg tablet, 25

2547C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	71.18	38.30	Alkeran [AS]

Alkyl sulfonates

▪ BUSULFAN

busulfan 2 mg tablet, 100

1128J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	87.64	38.30	Myleran [AS]

Nitrosoureas

▪ CARMUSTINE

Note Carmustine is not PBS-subsidised for use in conjunction with PBS-subsidised temozolomide.

Restricted benefit

Glioblastoma multiforme

Clinical criteria:

The condition must be suspected or confirmed at the time of initial surgery.

carmustine 7.7 mg implant, 8

8898H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	16670.18	38.30	Gliadel [EI]

Other alkylating agents

▪ TEMOZOLOMIDE

temozolomide 100 mg capsule, 5

8380C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	267.21	38.30	[a] APO-Temozolomide [TX] [a] Orion Temozolomide [ON] [a] Temodal [MK] [a] Temozolomide AN [EA]	[a] Astromide [FR] [a] Temizole 100 [QA] [a] Temozolomide Alphapharm [AF]

temozolomide 140 mg capsule, 5

9362R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	365.69	38.30	[a] APO-Temozolomide [TX] [a] Orion Temozolomide [ON] [a] Temodal [MK] [a] Temozolomide AN [EA]	[a] Astromide [FR] [a] Temizole 140 [QA] [a] Temozolomide Alphapharm [AF]

temozolomide 180 mg capsule, 5

2438H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	436.86	38.30	[a] APO-Temozolomide [TX] [a] Orion Temozolomide [ON]	[a] Astromide [FR] [a] Temodal [MK]

temozolomide 20 mg capsule, 5

8379B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	69.75	38.30	[a] APO-Temozolomide [TX] [a] Orion Temozolomide [ON] [a] Temodal [MK] [a] Temozolomide AN [EA]	[a] Astromide [FR] [a] Temizole 20 [QA] [a] Temozolomide Alphapharm [AF]

temozolomide 250 mg capsule, 5

8381D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	629.19	38.30	[a] APO-Temozolomide [TX] [a] Orion Temozolomide [ON] [a] Temodal [MK] [a] Temozolomide AN [EA]	[a] Astromide [FR] [a] Temizole 250 [QA] [a] Temozolomide Alphapharm [AF]

temozolomide 5 mg capsule, 5

8378Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	30.60	31.77	[a] APO-Temozolomide [TX] [a] Orion Temozolomide [ON] [a] Temodal [MK] [a] Temozolomide AN [EA]	[a] Astromide [FR] [a] Temizole 5 [QA] [a] Temozolomide Alphapharm [AF]

▪ TEMOZOLOMIDE

Note Temozolomide is not PBS-subsidised for use in conjunction with PBS-subsidised carmustine.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit
Glioblastoma multiforme
Treatment criteria:
Patient must be undergoing concomitant radiotherapy.

temozolomide 100 mg capsule, 5

8821G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*793.38	38.30	[a] APO-Temozolomide [TX] [a] Orion Temozolomide [ON] [a] Temodal [MK] [a] Temozolomide AN [EA]	[a] Astromide [FR] [a] Temizole 100 [QA] [a] Temozolomide Alphapharm [AF]

temozolomide 140 mg capsule, 5

9361Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*1088.82	38.30	[a] APO-Temozolomide [TX] [a] Orion Temozolomide [ON] [a] Temodal [MK] [a] Temozolomide AN [EA]	[a] Astromide [FR] [a] Temizole 140 [QA] [a] Temozolomide Alphapharm [AF]

temozolomide 180 mg capsule, 5

10062N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*1302.36	38.30	[a] APO-Temozolomide [TX] [a] Orion Temozolomide [ON]	[a] Astromide [FR] [a] Temodal [MK]

temozolomide 20 mg capsule, 5

8820F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*188.40	38.30	[a] APO-Temozolomide [TX] [a] Orion Temozolomide [ON] [a] Temodal [MK] [a] Temozolomide AN [EA]	[a] Astromide [FR] [a] Temizole 20 [QA] [a] Temozolomide Alphapharm [AF]

temozolomide 5 mg capsule, 5

8819E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*70.95	38.30	[a] APO-Temozolomide [TX] [a] Orion Temozolomide [ON] [a] Temodal [MK] [a] Temozolomide AN [EA]	[a] Astromide [FR] [a] Temizole 5 [QA] [a] Temozolomide Alphapharm [AF]

ANTIMETABOLITES

Folic acid analogues

▪ METHOTREXATE

methotrexate 10 mg tablet, 15

2272N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	22.52	23.69	Methoblastin [PF]

methotrexate 2.5 mg tablet, 30

1622J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	16.25	17.42	Methoblastin [PF]

methotrexate 5 mg/2 mL injection, 5 x 2 mL vials

2396D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	52.54	38.30	Hospira Pty Limited [HH]

▪ METHOTREXATE

Restricted benefit

Patients requiring doses greater than 20 mg per week

methotrexate 10 mg tablet, 50

1623K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	50.74	38.30	Methoblastin [PF]

▪ METHOTREXATE

Note For item codes 2395C and 1818Q, pharmaceutical benefits that have the form injection 50 mg in 2 mL are equivalent for the purposes of substitution.

METHOTREXATE Injection 50 mg in 2 mL, 1

1818Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	5	..	*50.33	38.30	[a] Methaccord [EA]	[a] Methotrexate MYX [OC]

methotrexate 50 mg/2 mL injection, 5 x 2 mL vials

2395C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	50.31	38.30	[a] Hospira Pty Limited [HH]

Purine analogues

▪ FLUDARABINE

fludarabine phosphate 10 mg tablet, 20

9184J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	929.93	38.30	Fludara [GZ]

▪ MERCAPTOPURINE

mercaptopurine 20 mg/mL oral liquid, 100 mL

10214N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	434.40	38.30	Allmercap [LM]

mercaptopurine 50 mg tablet, 25

1598D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	4	2	..	*242.41	38.30	Purinethol [AS]

▪ THIOGUANINE

thioguanine 40 mg tablet, 25

1233X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	218.90	38.30	Lanvis [AS]

Pyrimidine analogues

▪ CAPECITABINE

capecitabine 150 mg tablet, 60

8361C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	43.43	38.30	[a] Capecitabine Actavis [ED] [a] Capecitabine AN [EA] [a] Capecitabine MYX [OC] [a] Xelabine [QA]	[a] Capecitabine Alphapharm [AF] [a] Capecitabine-DRLA [RZ] [a] Capecitabine Sandoz [SZ]

capecitabine 500 mg tablet, 120

8362D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	215.89	38.30	[a] Capecitabine Actavis [ED] [a] Capecitabine AN [EA] [a] Capecitabine-DRLA [RZ] [a] Capecitabine MYX [OC] [a] Xelabine [QA]	[a] Capecitabine Alphapharm [AF] [a] Capecitabine Apotex [TX] [a] Capecitabine GH [GQ] [a] Capecitabine Sandoz [SZ] [a] Xeloda [RO]

PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

Vinca alkaloids and analogues

▪ VINORELBINE

Authority required

Advanced breast cancer

Clinical criteria:

Patient must have failed standard prior therapy, which includes an anthracycline.

Authority required

Locally advanced or metastatic non-small cell lung cancer

vinorelbine 20 mg capsule, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9009E	20	2	..	*1569.53	38.30	Navelbine [FB]

vinorelbine 30 mg capsule, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9010F	16	2	..	*1878.29	38.30	Navelbine [FB]

Podophyllotoxin derivatives

▪ ETOPOSIDE

etoposide 100 mg capsule, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1389D	1	..	..	383.25	38.30	Vepesid [BQ]

etoposide 50 mg capsule, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1396L	1	..	..	439.36	38.30	Vepesid [BQ]

CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

Anthracyclines and related substances

▪ IDARUBICIN

Restricted benefit

Acute myelogenous leukaemia (AML)

idarubicin hydrochloride 10 mg capsule, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2448W	3	..	..	*489.84	38.30	Zavedos [PF]

idarubicin hydrochloride 5 mg capsule, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2446R	3	..	..	*305.94	38.30	Zavedos [PF]

OTHER ANTINEOPLASTIC AGENTS

Monoclonal antibodies

▪ RITUXIMAB

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6011

Relapsed or refractory Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Maintenance therapy

Clinical criteria:

The treatment must be maintenance therapy, AND

Patient must have demonstrated a partial or complete response to re-induction treatment received immediately prior to this current Authority application, AND

Patient must not receive more than 8 cycles or 2 years duration of treatment, whichever comes first, under this restriction.

rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10709P	1	7	..	2850.65	38.30	Mabthera SC [RO]

▪ RITUXIMAB

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

5998

Relapsed or refractory low-grade B-cell non-Hodgkin's lymphoma

Treatment Phase: Re-induction treatment

Clinical criteria:

The treatment must be for re-induction treatment purposes only, AND

The condition must have relapsed or be refractory to treatment, AND

Patient must not receive more than 4 doses of rituximab in total, including intravenous and subcutaneous injections, and no more than 3 doses of subcutaneous rituximab under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 4 doses in total.

Authority required (STREAMLINED)

6039

Relapsed or refractory follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Re-induction treatment

Clinical criteria:

The treatment must be for re-induction treatment purposes only, AND

The condition must have relapsed or be refractory to treatment, AND

Patient must not receive more than 4 doses of rituximab in total, including intravenous and subcutaneous injections, and no more than 3 doses of subcutaneous rituximab under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 4 doses in total.

rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

10703H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	2850.65	38.30	Mabthera SC [RO]

▪ RITUXIMAB

Note A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6161

Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Maintenance therapy

Clinical criteria:

Patient must have demonstrated a partial or complete response to induction treatment with either R-CHOP or R-CVP regimens for previously untreated follicular B-cell Non-Hodgkin's lymphoma, received immediately prior to this current Authority application, AND

Patient must not have received bendamustine induction therapy, AND

The treatment must be maintenance therapy, AND

Patient must not receive more than 12 doses or 2 years duration of treatment, whichever comes first, under this restriction.

rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

10742J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	11	..	2850.65	38.30	Mabthera SC [RO]

▪ RITUXIMAB

Note A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6187

Previously untreated aggressive CD20 positive non-Hodgkin's lymphoma

Treatment Phase: Induction treatment

Clinical criteria:

The treatment must be in combination with PBS-subsidised chemotherapy, AND

The condition must be previously untreated, AND

The treatment must be for induction treatment purposes only, AND

Patient must not be eligible for stem cell transplantation if they have mantle cell lymphoma.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 8 doses in total.

Authority required (STREAMLINED)

6162

Previously untreated symptomatic indolent CD20 positive non-Hodgkin's lymphoma in combination with chemotherapy

Treatment Phase: Induction treatment

Clinical criteria:

The treatment must be in combination with PBS-subsidised chemotherapy, AND

The condition must be previously untreated, AND

The condition must be symptomatic, AND

The treatment must be for induction treatment purposes only, AND

Patient must not receive more than the number of cycles of treatment recommended by standard guidelines for the partner chemotherapy under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 8 doses in total.

rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

10719E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	6	..	2850.65	38.30	Mabthera SC [RO]

▪ TRASTUZUMAB

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Locally advanced HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

Clinical criteria:

Patient must commence treatment concurrently with neoadjuvant chemotherapy, AND

The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, AND

Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

HER2 positivity must be demonstrated by in situ hybridisation (ISH).

Authority applications for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Early Breast Cancer - PBS Supporting Information Form which includes:

(i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and

(ii) a copy of the signed patient acknowledgement form.

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

Authority required

Early HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

Clinical criteria:

Patient must commence treatment concurrently with adjuvant chemotherapy, AND

Patient must have undergone surgery, AND

The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, AND

Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

HER2 positivity must be demonstrated by in situ hybridisation (ISH).

Authority applications for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Early Breast Cancer - PBS Supporting Information Form which includes:

(i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and

(ii) a copy of the signed patient acknowledgement form.

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

Authority required

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, AND

The treatment must not be in combination with nab-paclitaxel, AND

The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Authority applications for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Late stage metastatic breast cancer Initial PBS authority application form which includes a copy of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH) and tick a box to state the patient has Stage IV disease.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will be authorised.

Note Special Pricing Arrangements apply.

trastuzumab 600 mg/5 mL injection, 5 mL vial

10721G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	2942.72	38.30	Herceptin SC [RO]

▪ TRASTUZUMAB

Authority required

Early HER2 positive breast cancer

Treatment Phase: Continuing treatment (3 weekly regimen)

Clinical criteria:

Patient must have previously received treatment with PBS-subsidised trastuzumab, AND

The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, AND

Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

Where a patient has a break in trastuzumab therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Locally advanced HER2 positive breast cancer

Treatment Phase: Continuing treatment (3 weekly regimen)

Clinical criteria:

Patient must have previously received treatment with PBS-subsidised trastuzumab, AND

The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, AND

Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, at 3 monthly intervals during treatment.

Where a patient has a break in trastuzumab therapy of more than 1 week but less than 6 weeks from when the last dose was due, authority approval will be granted for a new loading dose.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug for this condition, AND

The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Where a patient has a break in trastuzumab therapy of more than 1 week from when the last dose was due, authority approval will be granted for a new loading dose.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will be authorised.

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

Note Special Pricing Arrangements apply.

Authority required

HER2 positive breast cancer

Treatment Phase: Grandfathering treatment

Clinical criteria:

Patient must have previously received non-PBS-subsidised treatment with this drug for this condition before 1 July 2015, AND

The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will be authorised.

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

Note Special Pricing Arrangements apply.

trastuzumab 600 mg/5 mL injection, 5 mL vial

10682F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	2942.72	38.30	Herceptin SC [RO]

Protein kinase inhibitors

▪ AXITINIB

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug for this condition, AND

Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

axitinib 1 mg tablet, 28

10539Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*1119.79	38.30	Inlyta [PF]

axitinib 5 mg tablet, 28

10556N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*5186.87	38.30	Inlyta [PF]

▪ AXITINIB

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have progressive disease according to the Response Evaluation Criteria In Solid Tumours (RECIST) following first-line treatment with a tyrosine kinase inhibitor, AND

Patient must have a WHO performance status of 2 or less, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised treatment with this drug.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment.

axitinib 1 mg tablet, 28

10572K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*1119.79	38.30	Inlyta [PF]

axitinib 5 mg tablet, 28

10540R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*5186.87	38.30	Inlyta [PF]

▪ CRIZOTINIB

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Special Pricing Arrangements apply.

Note MANAGED ENTRY SCHEME
This medicine has been listed on the PBS via a Managed Entry Scheme (MES). This MES provides a mechanism to address the uncertainty over the size of the additional clinical benefit of this medicine while providing early access to those patients for whom there is a high clinical need.
Information about the benefits of this medicine in clinical practice will be collected, analysed and presented to the Pharmaceutical Benefits Advisory Committee (PBAC) for consideration in the near future.
Prescribers and patients must be aware that if a drug listed via a MES does not prove as beneficial in clinical practice as appeared in the clinical data presented to the PBAC, it may subsequently have its restriction modified, or may be removed from the PBS by the Commonwealth or at the request of the sponsor.
The relevant information for crizotinib is being collected about selected patients from their prescribing doctor. Patients are being selected on the grounds that they are crizotinib-naive when initiating PBS supply. Selection will stop when there are enough patients providing the relevant information.
Details of these arrangements are included in an information sheet that must be provided by the prescribing doctor to each selected patient receiving PBS-subsidy for this medicine.
For more information on Managed Entry Schemes, please visit http://www.pbs.gov.au/info/publication/factsheets/shared/framework-for-introduction-of-managed-entry-scheme-for-PBAC-submissions.
For more information on the PBAC's consideration of this medicine and its MES, please visit http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2014-11/crizotinib-psd-11-2014

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

Clinical criteria:

The treatment must be as monotherapy, AND

The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, AND

Patient must have a WHO performance status of 2 or less.

Population criteria:

Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing.

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

(1) a completed authority prescription form; and

(2) a completed ALK-Positive Non-Small-Cell Lung Cancer Authority Application - Supporting Information Form, which includes details of ALK gene rearrangement in tumour material by FISH testing.

Note Prescribers must provide the patient's unique identifier (in form XALK XXX, where XXX is a numerical value) when requesting PBS Authority approval. The patient's unique identifier is received upon registering the patient with the sponsor's crizotinib (Xalkori) Managed Entry Scheme website.
Please visit www.xalkorimes.com.au

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

The treatment must be as monotherapy, AND

Patient must have previously been issued with an authority prescription for this drug, AND

Patient must not have progressive disease.

Note Prescribers must provide the patient's unique identifier (in form XALK XXX, where XXX is a numerical value) when requesting PBS Authority approval. The patient's unique identifier was received upon registering the patient with the sponsor's crizotinib (Xalkori) Managed Entry Scheme website at the time of initiation.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Grandfathering treatment

Clinical criteria:

Patient must have received treatment with crizotinib for this condition prior to 1 July 2015, AND

The treatment must be as monotherapy, AND

The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, AND

Patient must have a WHO performance status of 2 or less, AND

Patient must not have progressive disease.

Population criteria:

Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material.

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

(1) a completed authority prescription form; and

(2) a completed ALK-Positive Non-Small-Cell Lung Cancer Authority Application - Supporting Information Form, which includes details of ALK gene rearrangement in tumour material by FISH testing.

crizotinib 200 mg capsule, 60

10323H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	7275.17	38.30	Xalkori [PF]

crizotinib 250 mg capsule, 60

10322G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	7275.17	38.30	Xalkori [PF]

▪ DABRAFENIB

Note A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

6044

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be positive for a BRAF V600 mutation, AND

The condition must not have been treated previously with PBS subsidised therapy; OR

Patient must have developed intolerance to another BRAF inhibitor of a severity necessitating permanent treatment withdrawal, AND

Patient must have a WHO performance status of 2 or less.

dabrafenib 50 mg capsule, 120

2963Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	5888.32	38.30	Tafinlar [NV]

dabrafenib 75 mg capsule, 120

2846T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	8759.04	38.30	Tafinlar [NV]

▪ DABRAFENIB

Note A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Note A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

6013

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug, AND

Patient must have stable or responding disease.

dabrafenib 50 mg capsule, 120

2954L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	5888.32	38.30	Tafinlar [NV]

dabrafenib 75 mg capsule, 120

10003L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	8759.04	38.30	Tafinlar [NV]

▪ DASATINIB

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe dasatinib should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesylate, dasatinib or nilotinib.

Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.

1. Initial treatment - imatinib mesylate, dasatinib and nilotinib

From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesylate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.

During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure of response.

2. Continuing treatment with imatinib mesylate - first-line

First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.

Second and subsequent authority applications for continuing therapy with imatinib mesylate may be made on the telephone by contacting Medicare Australia on 1800 700 720 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.

3. Continuing treatment with dasatinib or nilotinib - first-line

All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

4. For imatinib mesylate, dasatinib and nilotinib

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of second-line agents.

Where a patient has previously received PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

5. Authority approval requirements.

Response criteria to initial treatment with imatinib mesylate, dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesylate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

6. Definitions of response.

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.
A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
7. Definitions of loss of response.
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.
Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Authority required

Initial treatment, as the sole PBS-subsidised therapy, of a patient in the chronic phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, BCR-ABL tyrosine kinase, and who has a primary diagnosis of chronic myeloid leukaemia.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to dasatinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and

(4) a signed patient acknowledgement form

Authority required

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with dasatinib for the chronic phase of chronic myeloid leukaemia and who has demonstrated either a major cytogenetic response or less than 1% BCR-ABL level in the blood.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) demonstration of continued response to treatment as evidenced by either:

(a) major cytogenetic response [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided; or

(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided

dasatinib 100 mg tablet, 30

1416M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4761.44	38.30	Sprycel [BQ]

dasatinib 20 mg tablet, 60

1354G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	2948.51	38.30	Sprycel [BQ]

dasatinib 50 mg tablet, 60

1381Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4761.44	38.30	Sprycel [BQ]

dasatinib 70 mg tablet, 60

1415L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	5860.01	38.30	Sprycel [BQ]

▪ DASATINIB

Note Any queries concerning the arrangements to prescribe dasatinib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.
Applications for authority to prescribe dasatinib should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib. Imatinib mesylate is not approved for use in second or third line

treatment.

Patients are eligible for PBS-subsidised treatment with only one of dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent.

Nilotinib is not approved for patients in blast crisis.

1. Initial second line treatment

From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy.

During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.

2. Initial third line treatment

Third-line treatment with a TKI can only be approved when imatinib is used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent.

From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib providing the patient did not fail that drug as first or second line therapy and for nilotinib the patient is not in blast crisis.

3. Continuing treatment for second and third line treatment

All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.

4. Authority approval requirements.

Response criteria to initial treatment with dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

5. Definitions of response.

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

6. Definitions of loss of response.

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.

Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Authority required

Initial treatment, as the sole PBS-subsidised therapy, of a patient with chronic myeloid leukaemia in any disease phase who has failed an adequate trial of imatinib or nilotinib as first-line treatment.

Failure of an adequate trial of imatinib or nilotinib is defined as:

(i) Lack of response to initial imatinib or nilotinib therapy, defined as either:

— failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or nilotinib for patients initially treated in chronic phase; or

— failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or nilotinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

— failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or nilotinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or nilotinib therapy; OR

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or nilotinib therapy; OR

(iv) Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or nilotinib for any phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR

Blast crisis is defined as either:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

(2) Extramedullary involvement other than spleen and liver; OR

(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Chronic Myeloid Leukaemia - Second and Third Line - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report needs to be provided); and

(e) where there has been a loss of response to imatinib or nilotinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement

Authority required

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with dasatinib for chronic myeloid leukaemia, and who has demonstrated either a major cytogenetic response, or less than 1% BCR-ABL level in the blood, to dasatinib in the preceding 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Chronic Myeloid Leukaemia - Second and Third Line - Application Form for continuing treatment; and

(3) demonstration of continued response to treatment as evidenced by either:

(a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided; or

(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided

dasatinib 100 mg tablet, 30

9342Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	4761.44	38.30	Sprycel [BQ]

dasatinib 20 mg tablet, 60

2478K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	2948.51	38.30	Sprycel [BQ]

dasatinib 50 mg tablet, 60

2482P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	4761.44	38.30	Sprycel [BQ]

dasatinib 70 mg tablet, 60

2485T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	5860.01	38.30	Sprycel [BQ]

▪ DASATINIB

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

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Applications for authority to prescribe dasatinib should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note Dasatinib will only be subsidised for patients with acute lymphoblastic leukaemia who are not receiving concomitant PBS-subsidised imatinib mesylate and who are not appropriate for an allogeneic haemopoietic stem cell transplant.

Note No applications for increased repeats will be authorised.

Authority required

Initial treatment, as monotherapy, of a patient with acute lymphoblastic leukaemia (ALL) bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, who has failed treatment with chemotherapy AND imatinib and where appropriate, allogeneic haemopoietic stem cell transplantation.

Failure of treatment is defined as either:

(i) Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy and imatinib;

(ii) Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy and imatinib;

(iii) Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

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

(a) a completed authority prescription form; and

(b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided

Authority required

Initial treatment, as monotherapy, of a patient with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, who has been treated prior to 1 December 2007 and has failed treatment with chemotherapy and where appropriate, allogeneic haemopoietic stem cell transplantation.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

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

(a) a completed authority prescription form; and

(b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided

Authority required

Continuing treatment, as monotherapy, of a patient with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, where the patient has previously been issued with an authority prescription for dasatinib and does not have progressive disease.

Authority applications for continuing treatment may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

dasatinib 100 mg tablet, 30

9343R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	4761.44	38.30	Sprycel [BQ]

dasatinib 20 mg tablet, 60

9125G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	2948.51	38.30	Sprycel [BQ]

dasatinib 50 mg tablet, 60

9126H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	4761.44	38.30	Sprycel [BQ]

dasatinib 70 mg tablet, 60

9127J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	5860.01	38.30	Sprycel [BQ]

▪ ERLOTINIB

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

The treatment must be as monotherapy, AND

Patient must have previously been issued with an authority prescription for this drug prior to 1 August 2014, AND

Patient must not have progressive disease.

Population criteria:
Patient must have a wild type epidermal growth factor receptor (EGFR) gene; OR
Patient must have an epidermal growth factor receptor (EGFR) gene of unknown type.

erlotinib 100 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10019H	1	3	..	1172.86	38.30	Tarceva [RO]

erlotinib 150 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10025P	1	3	..	1432.83	38.30	Tarceva [RO]

erlotinib 25 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10028T	1	3	..	328.90	38.30	Tarceva [RO]

▪ ERLOTINIB

Authority required
Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Initial treatment
Clinical criteria:
The treatment must be as monotherapy, AND
The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, AND
Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR
Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal, AND
Patient must have a WHO performance status of 2 or less.
Population criteria:
Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.
Authority required
Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)
Treatment Phase: Continuing treatment
Clinical criteria:
The treatment must be as monotherapy, AND
Patient must have previously been issued with an authority prescription for this drug, AND
Patient must not have progressive disease.
Population criteria:
Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

erlotinib 100 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10020J	1	3	..	1172.86	38.30	Tarceva [RO]

erlotinib 150 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10014C	1	3	..	1432.83	38.30	Tarceva [RO]

erlotinib 25 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10022L	1	3	..	328.90	38.30	Tarceva [RO]

▪ EVEROLIMUS

Note Special Pricing Arrangements apply.

Authority required
Tuberous sclerosis complex (TSC)
Treatment Phase: Initial treatment
Clinical criteria:
The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
The condition must be visceral tumours associated with TSC, AND
The treatment must be the sole PBS-subsidised therapy for this condition, AND
Patient must not be a candidate for curative surgical resection.
Authority required

Tuberous sclerosis complex (TSC)
Treatment Phase: Continuing treatment
Clinical criteria:
The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
The condition must be visceral tumours associated with TSC, AND
The treatment must be the sole PBS-subsidised therapy for this condition, AND
Patient must have previously been treated with PBS-subsidised everolimus for this condition, AND
Patient must have demonstrated a response to prior treatment.

everolimus 2.5 mg tablet, 30

2818H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1403.90	38.30	Afinitor [NV]

▪ EVEROLIMUS

Note Special Pricing Arrangements apply.

Authority required
Tuberous sclerosis complex (TSC)
Treatment Phase: Initial treatment
Clinical criteria:
The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
The condition must be visceral tumours associated with TSC, AND
The treatment must be the sole PBS-subsidised therapy for this condition, AND
Patient must not be a candidate for curative surgical resection.

Authority required
Tuberous sclerosis complex (TSC)
Treatment Phase: Continuing treatment
Clinical criteria:
The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR
The condition must be visceral tumours associated with TSC, AND
The treatment must be the sole PBS-subsidised therapy for this condition, AND
Patient must have previously been treated with PBS-subsidised everolimus for this condition, AND
Patient must have demonstrated a response to prior treatment.

Authority required
Metastatic (Stage IV) breast cancer
Clinical criteria:
The condition must be hormone receptor positive, AND
The condition must be human epidermal growth factor receptor 2 (HER2) negative, AND
The condition must have acquired endocrine resistance as demonstrated by initial response and then recurrence or progression of disease after treatment with letrozole or anastrozole, AND
The treatment must be in combination with exemestane.
Population criteria:
Patient must not be pre-menopausal.

Note Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

everolimus 10 mg tablet, 30

2985D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	5276.87	38.30	Afinitor [NV]

everolimus 5 mg tablet, 30

2819J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	2711.87	38.30	Afinitor [NV]

▪ EVEROLIMUS

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Stage IV clear cell variant renal cell carcinoma (RCC)
Treatment Phase: Continuing treatment beyond 3 months
Clinical criteria:
Patient must have previously been issued with an authority prescription for this drug for this condition, AND
Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), AND
The treatment must be the sole PBS-subsidised therapy for this condition.
Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

Authority required

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug, AND

Patient must not have disease progression, AND

The treatment must be as monotherapy.

Patients who have progressive disease with this drug are no longer eligible for PBS-subsidised treatment with this drug.

everolimus 10 mg tablet, 30

10135K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	5276.87	38.30	Afinitor [NV]

everolimus 5 mg tablet, 30

10131F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	2711.87	38.30	Afinitor [NV]

▪ EVEROLIMUS

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have progressive disease according to the Response Evaluation Criteria In Solid Tumours (RECIST) following first-line treatment with a tyrosine kinase inhibitor, AND

Patient must have a WHO performance status of 2 or less, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.

Patients who have progressive disease with everolimus are no longer eligible for PBS-subsidised everolimus.

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

Authority required

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Initial treatment

Clinical criteria:

Patient must be symptomatic (despite somatostatin analogues); OR

Patient must have disease progression, AND

The treatment must be as monotherapy.

Disease progression must be documented in the patient's medical records.

Patients who have developed progressive disease on sunitinib are not eligible to receive PBS-subsidised everolimus.

Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus.

everolimus 10 mg tablet, 30

10132G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	5276.87	38.30	Afinitor [NV]

everolimus 5 mg tablet, 30

10133H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	2711.87	38.30	Afinitor [NV]

▪ GEFITINIB

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

Clinical criteria:

The treatment must be as monotherapy, AND

The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, AND

Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR

Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal, AND

Patient must have a WHO performance status of 2 or less.

Population criteria:

Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

The treatment must be as monotherapy, AND

Patient must have previously been issued with an authority prescription for this drug, AND

Patient must not have progressive disease.

gefitinib 250 mg tablet, 30

8769M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1432.83	38.30	Iressa [AP]

▪ IMATINIB

Note Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:
Dermatofibrosarcoma protuberans;
Hypereosinophilic syndrome;
Chronic eosinophilic leukaemia;
Myelodysplastic or myeloproliferative disorder;
Aggressive systemic mastocytosis with eosinophilia.

Note No applications for increased repeats will be authorised.

Authority required

Initial PBS-subsidised treatment of a patient with unresectable, locally recurrent or metastatic dermatofibrosarcoma protuberans.

Maximum dose: 800 mg per day.

(1) Where the application for authority to prescribe is being sought on the basis of unresectable tumour, written evidence in support of that claim must be provided; and

(2) Where the application for authority to prescribe is being sought on the basis of locally recurrent disease, the site of the local recurrence must be specified; and

(3) Where the application for authority to prescribe is being sought on the basis of metastatic disease, the site(s) of metastatic disease must be provided.

Applications for authorisation for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a signed patient acknowledgement

Authority required

Continuing PBS-subsidised treatment of a patient with unresectable, locally recurrent or metastatic dermatofibrosarcoma protuberans who has previously been issued with an authority prescription for imatinib and who has demonstrated a response, but whose disease remains unresectable.

Maximum dose: 800 mg per day.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a statement that the disease has not progressed on imatinib therapy

imatinib 100 mg tablet, 60

9172R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	1862.59	38.30	Glivec [NV]

imatinib 400 mg tablet, 30

9173T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	3598.23	38.30	Glivec [NV]

▪ IMATINIB

Note Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.
Written applications for authority to prescribe imatinib mesylate should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001
For the following diseases, written authority is required at initiation and for continuation:
Dermatofibrosarcoma protuberans;
Hypereosinophilic syndrome;
Chronic eosinophilic leukaemia;
Myelodysplastic or myeloproliferative disorder;
Aggressive systemic mastocytosis with eosinophilia.

Note No applications for increased repeats will be authorised.

Authority required

Initial PBS-subsidised treatment of a patient with hypereosinophilic syndrome or chronic eosinophilic leukaemia requiring treatment and confirmed to carry the FIP1L1-PDGFRA fusion gene.

Maximum dose: 400 mg per day.

Applications for authorisation for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene; and

(d) a copy of the full blood examination report confirming the presence of hypereosinophilic syndrome or chronic eosinophilic leukaemia; and

(e) details of organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and

(f) a signed patient acknowledgement

Authority required

Continuing PBS-subsidised treatment of a patient with hypereosinophilic syndrome or chronic eosinophilic leukaemia who has previously been issued with an authority prescription for imatinib and who has achieved and maintained a complete haematological response.

Maximum dose: 400 mg per day.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the full blood examination report which demonstrates a complete haematological response, with a normal eosinophil count; and

(d) a statement that the disease has not progressed on imatinib therapy

imatinib 100 mg tablet, 60

9174W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	1862.59	38.30	Glivec [NV]

imatinib 400 mg tablet, 30

9175X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	3598.23	38.30	Glivec [NV]

▪ IMATINIB

Note Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.
Written applications for authority to prescribe imatinib mesylate should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826

GPO Box 9826
HOBART TAS 7001
For the following diseases, written authority is required at initiation and for continuation:
Dermatofibrosarcoma protuberans;
Hypereosinophilic syndrome;
Chronic eosinophilic leukaemia;
Myelodysplastic or myeloproliferative disorder;
Aggressive systemic mastocytosis with eosinophilia.

Note No applications for increased repeats will be authorised.

Authority required

Initial PBS-subsidised treatment of a patient with a myelodysplastic or myeloproliferative disorder where:

(1) there is confirmed evidence of a platelet-derived growth factor receptor (PDGFR) gene re-arrangement either by standard karyotyping, or FISH or PDGFRB fusion gene transcript; and

(2) the patient has previously failed an adequate trial of one or more of the following conventional therapies:

— cytarabine;

— etoposide;

— hydroxyurea.

Maximum dose: 400 mg per day.

Applications for authorisation for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the pathology report confirming the platelet-derived growth factor receptor (PDGFR) gene re-arrangement; and

(d) a copy of the bone marrow biopsy report which demonstrates the presence of a myelodysplastic or myeloproliferative disorder; and

(e) details of the prior therapy trialled and the response; and

(f) a signed patient acknowledgement

Authority required

Continuing PBS-subsidised treatment of a patient with a PDGFRB fusion gene-positive myelodysplastic or myeloproliferative disorder who has previously been issued with an authority prescription for imatinib and who has demonstrated a complete haematological response.

Maximum dose: 400 mg per day.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the full blood examination report which demonstrates a complete haematological response; and

(d) a statement that the disease has not progressed on imatinib therapy

imatinib 100 mg tablet, 60

9176Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	1862.59	38.30	Glivec [NV]

imatinib 400 mg tablet, 30

9177B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	3598.23	38.30	Glivec [NV]

▪ IMATINIB

Note Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.
Written applications for authority to prescribe imatinib mesylate should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001
For the following diseases, written authority is required at initiation and for continuation:
Dermatofibrosarcoma protuberans;
Hypereosinophilic syndrome;
Chronic eosinophilic leukaemia;
Myelodysplastic or myeloproliferative disorder;
Aggressive systemic mastocytosis with eosinophilia.

Note No applications for increased repeats will be authorised.

Authority required

Initial PBS-subsidised treatment of a patient with aggressive systemic mastocytosis with eosinophilia where:

(1) there is confirmed evidence of the FIP1L1-PDGFRA fusion gene; and

(2) the patient has previously failed an adequate trial of one or more of the following conventional therapies:

— corticosteroids;

— hydroxyurea.

Maximum dose: 400 mg per day.

Applications for authorisation for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the pathology report confirming the presence of the FIP1L1-PDGFRA fusion gene; and

(d) a copy of the bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis and a copy of the full blood examination report demonstrating eosinophilia; and

(e) details of symptomatic organ involvement requiring treatment, including a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology reports as appropriate; and

(f) details of prior treatment trialled and the response; and

(g) a signed patient acknowledgement

Authority required

Continuing PBS-subsidised treatment of a patient with aggressive systemic mastocytosis confirmed to carry the FIP1L1-PDGFRA fusion gene, who has previously been issued with an authority prescription for imatinib and who has demonstrated a complete haematological response.

Maximum dose: 400 mg per day.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rare Diseases Imatinib PBS Authority Application - Supporting Information Form; and

(c) a copy of the full blood examination report which demonstrates a complete haematological response; and

(d) a statement that the disease has not progressed on imatinib therapy

imatinib 100 mg tablet, 60

9178C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	1862.59	38.30	Glivec [NV]

imatinib 400 mg tablet, 30

9179D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	3598.23	38.30	Glivec [NV]

▪ IMATINIB

Note Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:
Dermatofibrosarcoma protuberans;
Hypereosinophilic syndrome;
Chronic eosinophilic leukaemia;
Myelodysplastic or myeloproliferative disorder;
Aggressive systemic mastocytosis with eosinophilia.

Note Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)

Note No applications for increased repeats will be authorised.

Authority required

Initial PBS-subsidised treatment, for up to 3 months, of a patient with a metastatic or unresectable malignant gastrointestinal stromal tumour which has been histologically confirmed by the detection of CD117 on immunohistochemical staining.

Patients must commence treatment at a dose not exceeding 400 mg per day for at least 3 months. Authority prescriptions for a higher dose will not be approved during this initial 3 month treatment period.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Metastatic or Unresectable Gastrointestinal Stromal Tumour - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a copy of a pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining; and

(ii) a copy of the most recent (within 2 months of the application) computed tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s), including whether or not there is evidence of metastatic disease; and

(iii) where the application for authority to prescribe is being sought on the basis of an unresectable tumour, written evidence in support of that claim must be provided

Authority required

Continuing PBS-subsidised treatment, at a dose of up to 600 mg per day, of a patient with a metastatic or unresectable malignant gastrointestinal stromal tumour who has previously been issued with an authority prescription for this drug.

Applications for continuing treatment may be made by telephone (1800 700 270, hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

imatinib 100 mg tablet, 60

9111M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	1862.59	38.30	Glivec [NV]

imatinib 400 mg tablet, 30

9112N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	3598.23	38.30	Glivec [NV]

▪ IMATINIB

Authority required

Gastrointestinal stromal tumour

Treatment Phase: Initial treatment

Clinical criteria:

The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), AND

Patient must be at high risk of recurrence following complete surgical resection of primary GIST, AND

The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining, AND

The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy).

Applications for authorisation of initial treatment must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in Adjuvant Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form which includes the following:

(i) a copy of a pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining; and

(ii) a copy of the pathology report must include the size and mitotic rate of the tumour, and the date of tumour resection must be documented, which must not be more than 3 months prior to the date of this application.

High risk of recurrence is defined as:

Primary GIST greater than 5 cm with a mitotic count of greater than 5/50 high power fields (HPF); or

Primary GIST greater than 10 cm with any mitotic rate; or

Primary GIST with a mitotic count of greater than 10/50 HPF.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Any queries concerning patients who are enrolled on the Imatinib Compassionate Program may be directed to the Department of Human Services on 1800 700 270.

Authority required

Gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

Clinical criteria:

The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST), AND

Patient must be at high risk of recurrence following complete surgical resection of primary GIST, AND

The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy), AND

Patient must have previously been issued with an authority prescription for imatinib for adjuvant treatment following complete resection of primary GIST.

Applications for continuing therapy may be made by telephone.

Note Authority approval for continuing treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

imatinib 100 mg tablet, 60

5443L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	1862.59	38.30	Glivec [NV]

imatinib 400 mg tablet, 30

5444M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	3598.23	38.30	Glivec [NV]

▪ IMATINIB

Note Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:
Dermatofibrosarcoma protuberans;
Hypereosinophilic syndrome;
Chronic eosinophilic leukaemia;
Myelodysplastic or myeloproliferative disorder;
Aggressive systemic mastocytosis with eosinophilia.

Note No applications for increased repeats will be authorised.

Authority required

Treatment of patients in the accelerated phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia. Progress to the accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and

(c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criteria (1), (2), (3) and (5) above, or details of the dates of assessments in the case of progressive splenomegaly

Authority required

Treatment of patients in the blast phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, and who have a primary diagnosis of chronic myeloid leukaemia. Progress to myeloid blast crisis is defined as either:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

(2) Extramedullary involvement other than spleen and liver.

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in the Treatment of Chronic Myeloid Leukaemia - Supporting Information form, stating which of the above criteria are satisfied by the patient; and

(c) a copy of the confirming pathology report from an Approved Pathology Authority in the case of criterion (1) above, or details of the date of assessment in the case of extramedullary involvement

Authority required

Continuing treatment of patients with chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, where the patient has previously received PBS-subsidised treatment with imatinib mesylate of the accelerated phase of chronic myeloid leukaemia

Authority required

Continuing treatment of patients with chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, bcr-abl tyrosine kinase, where the patient has previously received PBS-subsidised treatment with imatinib mesylate of the blast phase of chronic myeloid leukaemia

imatinib 100 mg tablet, 60

9115R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	1862.59	38.30	Glivec [NV]

imatinib 400 mg tablet, 30

9116T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	3598.23	38.30	Glivec [NV]

▪ IMATINIB

Note Any queries concerning the arrangements to prescribe imatinib mesylate may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe imatinib mesylate should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

For the following diseases, written authority is required at initiation and for continuation:
Dermatofibrosarcoma protuberans;
Hypereosinophilic syndrome;
Chronic eosinophilic leukaemia;
Myelodysplastic or myeloproliferative disorder;
Aggressive systemic mastocytosis with eosinophilia.

Note Allogeneic stem cell transplantation is the preferred therapy for eligible patients achieving a complete remission of Philadelphia positive acute lymphoblastic leukaemia.

Note No applications for increased repeats will be authorised.

Authority required

Initial treatment in combination with chemotherapy as induction or consolidation of a newly diagnosed patient with acute lymphoblastic leukaemia (ALL) bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL.

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

(a) a completed authority prescription form; and

(b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and

(c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and

(d) a signed patient acknowledgement

Authority required

Initial treatment of a patient with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript BCR-ABL who was previously treated with imatinib mesylate under the Imatinib Compassionate Program and who meets all the PBS criteria.

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

(a) a completed authority prescription form; and

(b) a completed Acute Lymphoblastic Leukaemia Imatinib PBS Authority Application - Supporting Information Form; and

(c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided); and

(d) a signed patient acknowledgement

Authority required

Continuing treatment in combination with chemotherapy as maintenance of first complete remission of patients with acute lymphoblastic leukaemia bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL.

Authority applications for continuing treatment may be made by telephone to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Imatinib mesylate is available with a lifetime maximum of 24 months for continuing treatment with imatinib mesylate therapy for patients with acute lymphoblastic leukaemia reimbursed through the PBS.

Any queries concerning the arrangements to prescribe imatinib mesylate beyond 24 months may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

imatinib 100 mg tablet, 60

9123E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	1862.59	38.30	Glivec [NV]

imatinib 400 mg tablet, 30

9124F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	3598.23	38.30	Glivec [NV]

▪ IMATINIB

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial

Clinical criteria:

Patient must have a primary diagnosis of chronic myeloid leukaemia, AND

The condition must be in the chronic phase of chronic myeloid leukaemia, AND

The condition must be expressing the Philadelphia chromosome; OR

The condition must have the transcript BCR-ABL tyrosine kinase, AND

The treatment must be for first line therapy for this condition, AND

Patient must not have previously experienced a failure of response to the PBS-subsidised treatment with this drug for this condition; OR

Patient must have experienced intolerance, not a failure of response, to PBS-subsidised treatment with dasatinib as a first line therapy for this condition; OR

Patient must have experienced intolerance, not a failure of response, to PBS-subsidised treatment with nilotinib as a first line therapy for this condition, AND

The treatment must not exceed a total maximum of 18 months of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for authorisation must be in writing and must include:(1) a completed authority prescription form; and(2) a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form; and(3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and(4) a signed patient acknowledgement form

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of imatinib mesylate of 400 mg (base) daily. Continuing therapy is dependent on patients demonstrating a response to imatinib mesylate therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesylate, dasatinib or nilotinib.
Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.
1. Initial treatment - imatinib mesylate, dasatinib and nilotinib
From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesylate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.
During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure of response.
2. Continuing treatment with imatinib mesylate - first-line
First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.
Second and subsequent authority applications for continuing therapy with imatinib mesylate may be made on the telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.
3. Continuing treatment with dasatinib or nilotinib - first-line
All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and
(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.
4. For imatinib mesylate, dasatinib and nilotinib
During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of second-line agents.
Where a patient has previously received PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.

5. Authority approval requirements.
Response criteria to initial treatment with imatinib mesylate, dasatinib or nilotinib:
For the purposes of assessing response to PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesylate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
6. Definitions of response.
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.
A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
7. Definitions of loss of response.
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.
Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: First Continuing

Clinical criteria:

The condition must be in the chronic phase of chronic myeloid leukaemia, AND

Patient must have received initial PBS-subsidised treatment with this drug as a first line therapy for this condition; OR

Patient must have experienced intolerance, not a failure of response, to PBS-subsidised treatment with dasatinib as a first line therapy for this condition; OR

Patient must have experienced intolerance, not a failure of response, to PBS-subsidised treatment with nilotinib as a first line therapy for this condition, AND

Patient must have demonstrated a major cytogenic response; OR

Patient must have demonstrated a peripheral blood level of BCR-ABL of less than 1%, AND

The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

First continuing applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a response to treatment as evidenced by either:

(a) a major cytogenetic response [see Note explaining requirements]; or

(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements].

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesylate, dasatinib or nilotinib.
Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.
1. Continuing treatment with imatinib mesylate - first-line
First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.
Second and subsequent authority applications for continuing therapy with imatinib mesylate may be made on the telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.
2. Continuing treatment with dasatinib or nilotinib - first-line
All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and
(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.
3. For imatinib mesylate, dasatinib and nilotinib

During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of second-line agents.
Where a patient has previously received PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.
4. Authority approval requirements
Response criteria to initial treatment with imatinib mesylate, dasatinib or nilotinib:
For the purposes of assessing response to PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesylate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
5. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.
A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
6. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.
Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Subsequent continuing

Clinical criteria:

The condition must be in the chronic phase of chronic myeloid leukaemia, AND

Patient must have received initial continuing PBS-subsidised treatment with this drug as a first line therapy for this condition; OR

Patient must have experienced intolerance, not a failure of response, to PBS-subsidised treatment with dasatinib as a first line therapy for this condition; OR

Patient must have experienced intolerance, not a failure of response, to PBS-subsidised treatment with nilotinib as a first line therapy for this condition, AND

Patient must have maintained a major cytogenic response; OR

Patient must have maintained a peripheral blood level of BCR-ABL of less than 1%, AND

The treatment must not exceed a total maximum of 24 weeks of therapy with a PBS-subsidised treatment with a tyrosine kinase inhibitor for this condition under this restriction, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Second and subsequent authority applications for continuing therapy with imatinib mesylate may be made on the telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesylate, dasatinib or nilotinib.
Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.
1. Continuing treatment with imatinib mesylate - first-line
First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.
Second and subsequent authority applications for continuing therapy with imatinib mesylate may be made on the telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.
2. Continuing treatment with dasatinib or nilotinib - first-line
All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and
(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.
3. For imatinib mesylate, dasatinib and nilotinib
During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of second-line agents.
Where a patient has previously received PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at

any time failed to meet the response criteria whilst on that TKI agent.
4. Authority approval requirements
Response criteria to initial treatment with imatinib mesylate, dasatinib or nilotinib:
For the purposes of assessing response to PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesylate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
5. Definitions of response
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.
A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
6. Definitions of loss of response
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.
Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

imatinib 100 mg tablet, 60

9113P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1862.59	38.30	Glivec [NV]

imatinib 400 mg tablet, 30

9114Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	3598.23	38.30	Glivec [NV]

▪ LAPATINIB

Note No applications for increased maximum quantities will be authorised.
Note No applications for increased repeats will be authorised.

Authority required

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, AND

The treatment must be in combination with capecitabine, AND

Patient must have received prior therapy with a taxane for at least 3 cycles; OR

Patient must have developed intolerance to treatment with a taxane of a severity necessitating permanent treatment withdrawal, AND

The condition must have progressed following treatment with pertuzumab and trastuzumab in combination, AND

The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition, AND

The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Authority applications for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Late stage metastatic breast cancer Initial PBS authority application form which includes:

(i) a copy of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH) and tick a box to state the person has Stage IV disease;

(ii) date of last treatment with a taxane and total number of cycles;

(iii) a copy of the signed patient acknowledgement form;

(iv) dates of treatment with trastuzumab and pertuzumab; and

(v) date of demonstration of progression whilst on treatment with trastuzumab and pertuzumab.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug for this condition, AND

The treatment must be in combination with capecitabine, AND

Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, AND

The treatment must be the sole PBS-subsidised anti-HER2 therapy for this condition, AND

The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), at 3 monthly intervals during treatment.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

The treatment must not exceed a lifetime total of one continuous course.

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

lapatinib 250 mg tablet, 70

9148L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	..	*3225.91	38.30	Tykerb [NV]

▪ NILOTINIB

Note Any queries concerning the arrangements to prescribe nilotinib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.
Applications for authority to prescribe nilotinib should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for the chronic phase of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to imatinib mesylate, dasatinib or nilotinib.
Patients are eligible for PBS-subsidised treatment with only one TKI agent at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between TKI agents if they have not failed prior PBS-subsidised treatment with that agent.
1. Initial treatment - imatinib mesylate, dasatinib and nilotinib
From 1 April 2012, under the PBS, a patient will be able to be prescribed any of imatinib mesylate, dasatinib or nilotinib within the initial 18 month treatment period, as long as only one agent is used at a time and providing the patient has not failed to respond to any one of these TKIs.
During the initial 18 month treatment period, switching between approved first-line agents may only occur for reasons of intolerance, not failure of response.
2. Continuing treatment with imatinib mesylate - first-line
First continuing applications are to be written and must include a pathology report demonstrating the patient has responded to the initial course of treatment.
Second and subsequent authority applications for continuing therapy with imatinib mesylate may be made on the telephone by contacting Medicare Australia on 1800 700 720 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients must maintain a major cytogenetic response or have a peripheral blood BCR-ABL of less than 1% to receive continuing therapy.
3. Continuing treatment with dasatinib or nilotinib - first-line
All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:
(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and
(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

4. For imatinib mesylate, dasatinib and nilotinib
During continuing therapy beyond the initial 18 month treatment period, switching between approved first-line agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of second-line agents.
Where a patient has previously received PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib no approval will be granted for PBS-subsidised re-treatment in the chronic phase of chronic myeloid leukaemia, where that patient has at any time failed to meet the response criteria whilst on that TKI agent.
5. Authority approval requirements.
Response criteria to initial treatment with imatinib mesylate, dasatinib or nilotinib:
For the purposes of assessing response to PBS-subsidised treatment with imatinib mesylate, dasatinib or nilotinib either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with imatinib mesylate, dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
6. Definitions of response.
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.
A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
7. Definitions of loss of response.
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.
Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Authority required

Initial treatment, as the sole PBS-subsidised therapy, of a patient in the chronic phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript, BCR-ABL tyrosine kinase, and who has a primary diagnosis of chronic myeloid leukaemia.

Applications under this restriction will be limited to provide patients with a maximum of 18 months of therapy with dasatinib, imatinib or nilotinib from the date the first application for initial treatment was approved.

Patients should be commenced on a dose of nilotinib of 300 mg twice daily. Continuing therapy is dependent on patients demonstrating a response to nilotinib therapy following the initial 18 months of treatment and at 12 monthly intervals thereafter.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Chronic Myeloid Leukaemia - Chronic Phase, First Line - Supporting Information form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow; and

(4) a signed patient acknowledgement form

Authority required

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with nilotinib for the chronic phase of chronic myeloid leukaemia and who has demonstrated either a major cytogenetic response or less than 1% BCR-ABL level in the blood.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) demonstration of continued response to treatment as evidenced by either:

(a) major cytogenetic response [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided; or

(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining requirements]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided

NILOTINIB Capsule 150 mg (as hydrochloride monohydrate), 120

1309X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4252.30	38.30	Tasigna [NV]

▪ NILOTINIB

Note Any queries concerning the arrangements to prescribe nilotinib may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.
Applications for authority to prescribe nilotinib should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826

GPO Box 9826
HOBART TAS 7001

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tyrosine kinase inhibitors (TKI) agents for all phases of chronic myeloid leukaemia. Where the term TKI agent appears in the following notes and restrictions it refers to dasatinib or nilotinib. Imatinib mesylate is not approved for use in second or third line treatment.

Patients are eligible for PBS-subsidised treatment with only one of dasatinib or nilotinib at any one time and must not be receiving concomitant interferon alfa therapy. Eligible patients may only swap between these agents if they have not failed prior PBS-subsidised treatment with that agent.

Nilotinib is not approved for patients in blast crisis.

1. Initial second line treatment

From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib within the initial 18 month treatment period as second-line therapy, as long as only one agent is approved at a time and providing the patient did not fail that drug as first-line therapy.

During the initial 18 month treatment period, switching between approved second-line agents may only occur for reasons of intolerance, not failure of response.

2. Initial third line treatment

Third-line treatment with a TKI can only be approved when imatinib is used for first-line treatment. Patients will only be approved for PBS-subsidised treatment with one third-line agent.

From 1 April 2012, under the PBS, a patient will be able to be prescribed either dasatinib or nilotinib providing the patient did not fail that drug as first or second line therapy and for nilotinib the patient is not in blast crisis.

3. Continuing treatment for second and third line treatment

All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:

(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

During second line continuing treatment beyond the initial 18 month treatment period, switching between approved second line TKI agents may only occur for reason of intolerance. Where there is failure of response, switching may only occur through application for prescription of a third line agent.

4. Authority approval requirements.

Response criteria to initial treatment with dasatinib or nilotinib:

For the purposes of assessing response to PBS-subsidised treatment with dasatinib or nilotinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib or nilotinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).

5. Definitions of response.

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

6. Definitions of loss of response.

Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor (TKI) therapy.

Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Authority required

Initial treatment, as the sole PBS-subsidised therapy, of a patient with chronic myeloid leukaemia in chronic or accelerated phase who has failed an adequate trial of imatinib or dasatinib as first-line treatment.

Failure of an adequate trial of imatinib or dasatinib is defined as:

(i) Lack of response to initial imatinib or dasatinib therapy, defined as either:

— failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib for patients initially treated in chronic phase; or

— failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

— failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib therapy; OR

(iii) Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or dasatinib therapy; OR

(iv) Development of accelerated phase in a patient previously prescribed imatinib or dasatinib for the chronic phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome); OR

(v) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib or dasatinib therapy in patients with accelerated phase chronic myeloid leukaemia, provided that blast crisis has been excluded on bone marrow biopsy.

Patients should be commenced on a dose of nilotinib of 400 mg twice daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to nilotinib therapy or a peripheral blood BCR-ABL level of less than 1% within 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Chronic Myeloid Leukaemia - Second and Third Line - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report needs to be provided); and

(e) where there has been a loss of response to imatinib or dasatinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement

Authority required

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial PBS-subsidised treatment with nilotinib for chronic myeloid leukaemia, and who has demonstrated either a major cytogenetic response, or less than 1% BCR-ABL level in the blood, to dasatinib in the preceding 18 months and thereafter at 12 monthly intervals.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Chronic Myeloid Leukaemia - Second and Third Line - Application Form for continuing treatment; and

(3) demonstration of continued response to treatment as evidenced by either:

(a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided; or

(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided

NILOTINIB Capsule 200 mg (as hydrochloride monohydrate), 120

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9171Q	1	5	..	5586.36	38.30	Tasigna [NV]

▪ PAZOPANIB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a WHO performance status of 2 or less, AND

Patient must have received prior chemotherapy treatment including an anthracycline, AND

Patient must not have received prior treatment with an angiogenesis inhibitor, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Patient must not have any of the following conditions:

adipocytic soft tissue sarcoma;

gastrointestinal stromal tumour (GIST);

rhabdomyosarcoma other than alveolar or pleomorphic;

chondrosarcoma;

osteosarcoma;

Ewings tumour/primitive neuroectodermal tumour;

dermofibromatosis sarcoma protuberans;

inflammatory myofibroblastic sarcoma;

malignant mesothelioma;

mixed mesodermal tumour of the uterus.

The authority application must be made in writing.

pazopanib 200 mg tablet, 90

10042M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	3542.33	38.30	Votrient [NV]

pazopanib 400 mg tablet, 60

10041L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	4674.15	38.30	Votrient [NV]

▪ PAZOPANIB

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

Patient must have previously been issued with an authority prescription for pazopanib, AND

Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for continuing therapy may be made by telephone.

pazopanib 200 mg tablet, 90

10047T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	3542.33	38.30	Votrient [NV]

pazopanib 400 mg tablet, 60

10043N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	4674.15	38.30	Votrient [NV]

▪ PAZOPANIB

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Advanced (unresectable and/or metastatic) soft tissue sarcoma

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

Patient must have previously been issued with an authority prescription for pazopanib, AND

Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), AND

Patient must require dose adjustment, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Applications for continuing therapy may be made by telephone.

pazopanib 200 mg tablet, 30

10054E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	1247.94	38.30	Votrient [NV]

pazopanib 400 mg tablet, 30

10052C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	2410.51	38.30	Votrient [NV]

▪ PAZOPANIB

Note Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.

Note Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.
Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.
Note Special Pricing Arrangements apply.

Authority required
Stage IV clear cell variant renal cell carcinoma (RCC)
Treatment Phase: Continuing treatment beyond 3 months
Clinical criteria:
Patient must have previously been issued with an authority prescription for pazopanib, AND
Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), AND
Patient must require dose adjustment, AND
The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

pazopanib 200 mg tablet, 30

2232L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1247.94	38.30	Votrient [NV]

pazopanib 400 mg tablet, 30

2201W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	2410.51	38.30	Votrient [NV]

▪ PAZOPANIB

Note Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised pazopanib.
Note Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Stage IV clear cell variant renal cell carcinoma (RCC)
Treatment Phase: Initial treatment
Clinical criteria:
Patient must meet the Memorial Sloan Kettering Cancer Centre (MSKCC) low to intermediate risk group criteria, AND
Patient must have a WHO performance status of 2 or less, AND
The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.
Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.

pazopanib 200 mg tablet, 90

2029T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	3542.33	38.30	Votrient [NV]

pazopanib 400 mg tablet, 60

2030W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	4674.15	38.30	Votrient [NV]

▪ PAZOPANIB

Note Patients who have progressive disease with pazopanib are no longer eligible for PBS-subsidised pazopanib.
Note Special Pricing Arrangements apply.

Authority required
Stage IV clear cell variant renal cell carcinoma (RCC)
Treatment Phase: Continuing treatment beyond 3 months
Clinical criteria:
Patient must have previously been issued with an authority prescription for pazopanib, AND
Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), AND
The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.
Note Patients who have progressive disease on sunitinib are not eligible to receive PBS-subsidised pazopanib.
Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have been receiving treatment with pazopanib prior to 1 October 2012, AND

The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

pazopanib 200 mg tablet, 90

2034C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	3542.33	38.30	Votrient [NV]

pazopanib 400 mg tablet, 60

2035D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4674.15	38.30	Votrient [NV]

▪ PONATINIB

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Patients are eligible for PBS-subsidised treatment with only one of imatinib, dasatinib, nilotinib or ponatinib at any one time and must not be receiving concomitant interferon alfa therapy.
1. Continuing treatment
All continuing applications are to be written and must include a pathology report demonstrating the patient has responded to PBS-subsidised treatment as follows:
(i) within 18 months of the commencement of treatment, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and
(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.
2. Authority approval requirements.
Response criteria to initial treatment with ponatinib:
For the purposes of assessing response to PBS-subsidised treatment with ponatinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted within 18 months of the commencement of treatment with dasatinib, nilotinib or ponatinib (patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% is demonstrable by 18 months are eligible to receive continuing treatment with that agent).
3. Definitions of response.
A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.
A peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.
4. Definitions of loss of response.
Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing tyrosine kinase inhibitor therapy.
Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing tyrosine kinase inhibitor therapy.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

Clinical criteria:

The treatment must be the sole PBS-subsidised therapy for this condition, AND

Patient must have failed an adequate trial of dasatinib; OR

Patient must have developed intolerance to dasatinib of a severity necessitating permanent treatment withdrawal, AND

Patient must have failed an adequate trial of nilotinib; OR

Patient must have developed intolerance to nilotinib of a severity necessitating permanent treatment withdrawal; OR

Patient must not be eligible for PBS-subsidised treatment with nilotinib because the patient has a blast crisis.

Failure of an adequate trial of dasatinib or nilotinib is defined as:

1. Lack of response to dasatinib or nilotinib therapy, defined as either:

(i) failure to achieve a haematological response after a minimum of 3 months therapy with dasatinib or nilotinib; or

(ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy with dasatinib or nilotinib as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

(iii) failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with dasatinib or nilotinib; OR

2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing dasatinib or nilotinib therapy; OR

3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing dasatinib or nilotinib therapy; OR

4. Development of accelerated phase or blast crisis in a patient previously prescribed dasatinib or nilotinib for any phase of chronic myeloid leukaemia; OR

5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during dasatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

3. Peripheral basophils greater than or equal to 20%; or

4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

2. Extramedullary involvement other than spleen and liver.

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

1. a completed authority prescription form;

2. a completed Chronic Myeloid Leukaemia - ponatinib Initial PBS authority application form;

3. a signed patient acknowledgement;

4. a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale. (The date of the relevant pathology report, which should be within the previous 6 months, needs to be provided); and

5. where there has been a loss of response to dasatinib or nilotinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Initial treatment

Clinical criteria:

The treatment must be the sole PBS-subsidised therapy for this condition, AND

Patient must be expressing the T315I mutation, AND

Patient must have failed an adequate trial of imatinib; OR

Patient must have failed an adequate trial of dasatinib; OR

Patient must have failed an adequate trial of nilotinib.

Failure of an adequate trial of imatinib or dasatinib or nilotinib is defined as:

1. Lack of response to imatinib or dasatinib or nilotinib therapy, defined as either:

(i) failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib or nilotinib; or

(ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib or nilotinib as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

(iii) failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib or nilotinib; OR

2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib or nilotinib therapy; OR

3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or dasatinib or nilotinib therapy; OR

4. Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or dasatinib or nilotinib for any phase of chronic myeloid leukaemia; OR

5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during imatinib or dasatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or

3. Peripheral basophils greater than or equal to 20%; or

4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Blast crisis is defined as either:

1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

2. Extramedullary involvement other than spleen and liver.

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

1. a completed authority prescription form; and

2. a completed Chronic Myeloid Leukaemia - ponatinib Initial PBS authority application form; and

3. a signed patient acknowledgement; and

4. a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale and evidence of the T315I mutation. (The date of the relevant pathology report(s), which should be within the previous 6 months, need(s) to be provided); and

5. where there has been a loss of response to imatinib or dasatinib or nilotinib, a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.

Authority required

Chronic Myeloid Leukaemia (CML)

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug for this condition, AND

The treatment must be the sole PBS-subsidised therapy for this condition, AND

Patient must have demonstrated either a major cytogenetic response, or less than 1% BCR-ABL level in the blood, to ponatinib within 18 months of commencement and at no greater than 12 month intervals thereafter.

Applications for authorisation must be in writing and must include:

1. a completed authority prescription form; and

2. a completed Chronic Myeloid Leukaemia Continuing PBS authority application Supporting information form; and

3. demonstration of continued response to treatment as evidenced by either:

(a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided; or

(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months (or 18 months for the initial supply), only the date of the relevant pathology report needs to be provided.

ponatinib 15 mg tablet, 60

10520Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	5755.48	38.30	Iclusig [TS]

ponatinib 45 mg tablet, 30

10530F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	6474.92	38.30	Iclusig [TS]

▪ PONATINIB

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

The treatment must be the sole PBS-subsidised therapy for this condition, AND

Patient must be expressing the T315I mutation, AND

Patient must have failed treatment with chemotherapy, with or without another tyrosine kinase inhibitor, AND

Patient must have failed allogeneic haemopoietic stem cell transplantation (where appropriate).

Failure of treatment is defined as either:

1. Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy, with or without another tyrosine kinase inhibitor;

2. Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy, with or without another tyrosine kinase inhibitor;

3. Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.

Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.

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

1. a completed authority prescription form; and

2. a completed Acute Lymphoblastic Leukaemia - ponatinib Initial PBS authority application form; and

3. a signed patient acknowledgement; and

4. a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript.; and evidence of the T315I mutation. The date of the relevant pathology report(s), which should be within the previous 6 months, need(s) to be provided

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug for this condition, AND

The treatment must be the sole PBS-subsidised therapy for this condition, AND

Patient must not have progressive disease.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

ponatinib 15 mg tablet, 60

10523W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	5755.48	38.30	Iclusig [TS]

ponatinib 45 mg tablet, 30

10524X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	6474.92	38.30	Iclusig [TS]

▪ RUXOLITINIB

Note Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) OR the Dynamic International Prognostic Scoring System (DIPSS) OR the Age-Adjusted DIPSS.

Note Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Programs
Reply Paid 9826
HOBART TAS 7001

Note No increase in the maximum quantity may be authorised for the 15 mg and 20 mg dose strengths.

Note Special Pricing Arrangements apply.

Authority required

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis.

Note The authority application must be made in writing and must include:
(1) A completed authority prescription form; and
(2) A completed Myelofibrosis Authority Application Supporting Information Form, which includes all of the following:
(a) A copy of the bone marrow biopsy report confirming diagnosis of myelofibrosis; and
(b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.

Authority required

Intermediate-1 risk myelofibrosis

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, AND

Patient must have severe disease-related symptoms that are resistant, refractory or intolerant to available therapy.

Note The authority application must be made in writing and must include:
(1) A completed authority prescription form; and
(2) A completed Myelofibrosis Authority Application Supporting Information Form, which includes all of the following:
a) A copy of the bone marrow biopsy report confirming diagnosis of myelofibrosis;
b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS; and
c) A confirmation that the patient's disease related symptoms are resistant, refractory or intolerant to available therapy.

ruxolitinib 15 mg tablet, 56

10619X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	5146.87	38.30	Jakavi [NV]

ruxolitinib 20 mg tablet, 56

10618W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	5146.87	38.30	Jakavi [NV]

ruxolitinib 5 mg tablet, 56

10614P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*5146.87	38.30	Jakavi [NV]

▪ RUXOLITINIB

Note Risk of myelofibrosis is defined in accordance with the Myelofibrosis International Prognostic Scoring System (IPSS) OR the Dynamic International Prognostic Scoring System (DIPSS) OR the Age-Adjusted DIPSS.

Note No increase in the maximum quantity may be authorised for the 15 mg and 20 mg dose strengths.

Note Special Pricing Arrangements apply.

Authority required

High risk and intermediate-2 risk myelofibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, AND

Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Intermediate-1 risk myelofibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, AND

Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

High risk, intermediate-2 risk and intermediate-1 risk myelofibrosis

Treatment Phase: Grandfathering treatment

Clinical criteria:

The condition must be primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, AND

Patient must have previously received non-PBS-subsidised treatment with this drug for this condition before 1 February 2016.

Note The authority application must be made in writing and must include:
(1) A completed authority prescription form; and
(2) A completed Myelofibrosis Authority Application Supporting Information Form, which includes all of the following:
a) A copy of the bone marrow biopsy report confirming diagnosis of myelofibrosis; and
b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS.
(3) Details of previous ruxolitinib treatment, including all of the following:
a) The date which treatment with ruxolitinib was initiated;
b) A confirmation that the PBS restriction criteria for the relevant risk category was met at the time of initiation; and
c) The method by which ruxolitinib treatment was accessed at the time of initiation (e.g. through a compassionate use program).

Note Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Programs
Reply Paid 9826
HOBART TAS 7001

ruxolitinib 15 mg tablet, 56

10615Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	5146.87	38.30	Jakavi [NV]

ruxolitinib 20 mg tablet, 56

10617T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	5146.87	38.30	Jakavi [NV]

ruxolitinib 5 mg tablet, 56

10616R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*5146.87	38.30	Jakavi [NV]

▪ SORAFENIB

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have progressive disease according to the Response Evaluation Criteria In Solid Tumours (RECIST) following first-line treatment with a tyrosine kinase inhibitor, AND

Patient must have a WHO performance status of 2 or less, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised treatment with this drug.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

sorafenib 200 mg tablet, 60

10226F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	2	..	*6142.05	38.30	Nexavar [BN]

▪ SORAFENIB

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug for this condition, AND

Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), AND

The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

sorafenib 200 mg tablet, 60

10242C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*6142.05	38.30	Nexavar [BN]

▪ SORAFENIB

Note Sorafenib is not PBS-subsidised for adjunctive treatment after resection, ablation or chemoembolization.
Sorafenib is not PBS-subsidised for maintenance therapy after disease progression.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)
4230
Advanced Barcelona Clinic Liver Cancer Stage C hepatocellular carcinoma
Treatment Phase: Initial
Clinical criteria:
The treatment must be the sole PBS-subsidised therapy for this condition, AND
Patient must have a WHO performance status of 2 or less, AND
Patient must have Child Pugh class A.
Authority required (STREAMLINED)
4234
Advanced Barcelona Clinic Liver Cancer Stage C hepatocellular carcinoma
Treatment Phase: Continuing
Clinical criteria:
The treatment must be the sole PBS-subsidised therapy for this condition, AND
Patient must have previously been treated with PBS-subsidised sorafenib, AND
Patient must not have progressive disease.

sorafenib 200 mg tablet, 60

9380Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	2	..	*6142.05	38.30	Nexavar [BN]

▪ SUNITINIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)
Treatment Phase: Initial treatment
Clinical criteria:
Patient must be symptomatic (despite somatostatin analogues); OR
Patient must have disease progression, AND
The treatment must be as monotherapy.
Disease progression must be documented in the patient's medical records.
Patients who have developed progressive disease on everolimus are not eligible to receive PBS-subsidised sunitinib for this condition.
Patients who have developed intolerance to everolimus of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib.

sunitinib 12.5 mg capsule, 28

10004M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	1736.08	38.30	Sutent [PF]

sunitinib 25 mg capsule, 28

2959R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	3353.50	38.30	Sutent [PF]

sunitinib 37.5 mg capsule, 28

10464R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	4956.95	38.30	Sutent [PF]

sunitinib 50 mg capsule, 28

2837H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	6560.40	38.30	Sutent [PF]

▪ SUNITINIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)
Treatment Phase: Continuing treatment
Clinical criteria:
Patient must have previously been issued with an authority prescription for this drug, AND

Patient must not have disease progression, AND
The treatment must be as monotherapy.
Patients who have progressive disease with this drug are no longer eligible for PBS-subsidised treatment with this drug.

sunitinib 12.5 mg capsule, 28

10009T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	1736.08	38.30	Sutent [PF]

sunitinib 25 mg capsule, 28

2842N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	3353.50	38.30	Sutent [PF]

sunitinib 37.5 mg capsule, 28

10473F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	4956.95	38.30	Sutent [PF]

sunitinib 50 mg capsule, 28

10010W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	6560.40	38.30	Sutent [PF]

▪ SUNITINIB

Note Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.
Note Patients who have developed progressive disease on pazopanib are not eligible to receive PBS-subsidised sunitinib.
Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.
Note Special Pricing Arrangements apply.

Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)
Treatment Phase: Continuing treatment beyond 3 months
Clinical criteria:
Patient must have previously been issued with an authority prescription for sunitinib, AND
Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), AND
The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.

sunitinib 12.5 mg capsule, 28

9420T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	1736.08	38.30	Sutent [PF]

sunitinib 25 mg capsule, 28

9421W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	3353.50	38.30	Sutent [PF]

sunitinib 37.5 mg capsule, 28

10459L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	4956.95	38.30	Sutent [PF]

sunitinib 50 mg capsule, 28

9422X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	6560.40	38.30	Sutent [PF]

▪ SUNITINIB

Note Patients who have developed intolerance to pazopanib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib.
Note Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)
Treatment Phase: Initial treatment
Clinical criteria:
Patient must meet the Memorial Sloan Kettering Cancer Centre (MSKCC) low to intermediate risk group criteria, AND

Patient must have a WHO performance status of 2 or less, AND
The treatment must be the sole PBS-subsidised tyrosine kinase inhibitor therapy for this condition.
Patients who have developed progressive disease on pazopanib are not eligible to receive PBS-subsidised sunitinib.

sunitinib 12.5 mg capsule, 28

9417P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	1736.08	38.30	Sutent [PF]

sunitinib 25 mg capsule, 28

9418Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	3353.50	38.30	Sutent [PF]

sunitinib 37.5 mg capsule, 28

10504W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	4956.95	38.30	Sutent [PF]

sunitinib 50 mg capsule, 28

9419R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	6560.40	38.30	Sutent [PF]

▪ SUNITINIB

Note Sunitinib malate is not PBS-subsidised for the treatment of patients with resectable malignant gastrointestinal stromal tumours.

Note Any queries concerning patients who are enrolled on the Sunitinib Compassionate Program may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required
Metastatic or unresectable malignant gastrointestinal stromal tumour
Treatment Phase: Initial treatment
Clinical criteria:
The treatment must be as monotherapy, AND
Patient must have a WHO performance status of 2 or less, AND
Patient must have previously failed or be intolerant to imatinib mesylate.
Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Sunitinib Malate (Sutent) PBS Authority Application for Use in the Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form; and
(3) a signed patient acknowledgement.
Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

Authority required
Metastatic or unresectable malignant gastrointestinal stromal tumour
Treatment Phase: Continuing treatment
Clinical criteria:
Patient must have previously been issued with an authority prescription for this drug, AND
The treatment must be as monotherapy, AND
Patient must have a WHO performance status of 2 or less, AND
Patient must not have progressive disease.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.

Note Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS subsidised imatinib after progression on this drug

sunitinib 12.5 mg capsule, 28

9488J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	1736.08	38.30	Sutent [PF]

sunitinib 25 mg capsule, 28

9489K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	3353.50	38.30	Sutent [PF]

sunitinib 37.5 mg capsule, 28

10503T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	4956.95	38.30	Sutent [PF]

sunitinib 50 mg capsule, 28

9490L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	6560.40	38.30	Sutent [PF]

▪ TRAMETINIB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note MANAGED ENTRY SCHEME

This medicine has been listed on the PBS via a Managed Entry Scheme (MES). This MES provides a mechanism to address the uncertainty over the size of the additional clinical benefit of this medicine while providing early access to those patients for whom there is a high clinical need.
Information about the benefits of this medicine in clinical practice will be collected, analysed and presented to the Pharmaceutical Benefits Advisory Committee (PBAC) for consideration in the near future.
Prescribers and patients must be aware that if a drug listed via a MES does not prove as beneficial in clinical practice as appeared in the clinical data presented to the PBAC, it may subsequently have its restriction modified, or may be removed from the PBS by the Commonwealth or at the request of the sponsor.
In the case of trametinib, the relevant information is being collected from an ongoing clinical trial outside the PBS.
Details of these arrangements are included in an information sheet that must be provided by the prescribing doctor to each patient receiving PBS-subsidy for this medicine.
For more information on Managed Entry Schemes, please visit http://www.pbs.gov.au/info/publication/factsheets/shared/framework-for-introduction-of-managed-entry-scheme-for-PBAC-submissions.
For more information on the PBAC's consideration of this medicine and its MES, please visit http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2014-11/trametinib-psd-11-2014

Authority required (STREAMLINED)

6021

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

Clinical criteria:

Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition, AND

Patient must not have had progressive disease when treated with a BRAF inhibitor.

trametinib 2 mg tablet, 30

10382K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	8759.04	38.30	Mekinist [NV]

trametinib 500 microgram tablet, 30

10403M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	3	3	..	*6605.97	38.30	Mekinist [NV]

▪ TRAMETINIB

Note A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note MANAGED ENTRY SCHEME

This medicine has been listed on the PBS via a Managed Entry Scheme (MES). This MES provides a mechanism to address the uncertainty over the size of the additional clinical benefit of this medicine while providing early access to those patients for whom there is a high clinical need.
Information about the benefits of this medicine in clinical practice will be collected, analysed and presented to the Pharmaceutical Benefits Advisory Committee (PBAC) for consideration in the near future.
Prescribers and patients must be aware that if a drug listed via a MES does not prove as beneficial in clinical practice as appeared in the clinical data presented to the PBAC, it may subsequently have its restriction modified, or may be removed from the PBS by the Commonwealth or at the request of the sponsor.
In the case of trametinib, the relevant information is being collected from an ongoing clinical trial outside the PBS.
Details of these arrangements are included in an information sheet that must be provided by the prescribing doctor to each patient receiving PBS-subsidy for this medicine.
For more information on Managed Entry Schemes, please visit

http://www.pbs.gov.au/info/publication/factsheets/shared/framework-for-introduction-of-managed-entry-scheme-for-PBAC-submissions.
For more information on the PBAC's consideration of this medicine and its MES, please visit
http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2014-11/trametinib-psd-11-2014

Authority required (STREAMLINED)

6029

Unresectable Stage III or Stage IV malignant melanoma
Treatment Phase: Continuing treatment
Clinical criteria:
Patient must have previously been issued with an authority prescription for this drug, AND
Patient must be receiving PBS-subsidised dabrafenib concomitantly for this condition, AND
Patient must have stable or responding disease.

trametinib 2 mg tablet, 30

10405P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	8759.04	38.30	Mekinist [NV]

trametinib 500 microgram tablet, 30

10385N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	3	5	..	*6605.97	38.30	Mekinist [NV]

Other antineoplastic agents

▪ HYDROXYUREA

hydroxyurea 500 mg capsule, 100

3093T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	70.91	38.30	Hydrea [BQ]

▪ ENDOCRINE THERAPY

HORMONES AND RELATED AGENTS

Progestogens

▪ MEDROXYPROGESTERONE

Restricted benefit

Advanced breast cancer
Clinical criteria:
The condition must be hormone receptor positive.

medroxyprogesterone acetate 500 mg tablet, 30

2728N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	135.53	38.30	Provera [PF]

▪ MEDROXYPROGESTERONE

Restricted benefit

Breast cancer
Clinical criteria:
The condition must be hormone receptor positive.

Restricted benefit

Endometrial cancer

medroxyprogesterone acetate 100 mg tablet, 100

2725K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	98.05	38.30	Provera [PF]

medroxyprogesterone acetate 200 mg tablet, 60

2316X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	110.11	38.30	Provera [PF]

medroxyprogesterone acetate 250 mg tablet, 60

2727M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	135.53	38.30	Provera [PF]

▪ MEGESTROL

megestrol acetate 160 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2734X	1	2	..	76.90	38.30	Megace [QA]

Gonadotropin releasing hormone analogues

▪ GOSERELIN

Restricted benefit
Carcinoma of the prostate
Clinical criteria:
The condition must be locally advanced (stage C); OR
The condition must be metastatic (stage D).

goserelin 10.8 mg implant, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8093Y	1	1	..	1049.93	38.30	Zoladex 10.8 Implant [AP]

▪ GOSERELIN

Restricted benefit
Carcinoma of the prostate
Clinical criteria:
The condition must be locally advanced (stage C); OR
The condition must be metastatic (stage D).

Restricted benefit
Endometriosis
Clinical criteria:
The condition must be visually proven, AND
The treatment must be for the short-term (up to 6 months).

Note Only 1 course of not more than 6 months' therapy will be authorised.

Restricted benefit
Breast cancer
Clinical criteria:
The condition must be hormone receptor positive.

goserelin 3.6 mg implant, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1454M	1	5	..	307.53	38.30	Zoladex Implant [AP]

▪ GOSERELIN (&) BICALUTAMIDE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit
Carcinoma of the prostate
Clinical criteria:
The condition must be metastatic (stage D), AND
Patient must require a combination of an antiandrogen and a GnRH (LH-RH) agonist.

goserelin 10.8 mg implant [1 implant] (&) bicalutamide 50 mg tablet [28 tablets], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9065D	‡1	..	..	1188.79	38.30	ZolaCos CP 10.8/50(28) [AP]

goserelin 10.8 mg implant [1 implant] (&) bicalutamide 50 mg tablet [84 tablets], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9066E	‡1	1	..	1466.52	38.30	ZolaCos CP 10.8/50(84) [AP]

goserelin 3.6 mg implant [1 implant] (&) bicalutamide 50 mg tablet [28 tablets], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9064C	‡1	5	..	456.84	38.30	ZolaCos CP 3.6/50 [AP]

▪ LEUPRORELIN

Authority required (STREAMLINED)
4871
Central precocious puberty
Treatment Phase: Continuing treatment
Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug for this condition.
Treatment criteria:
Must be treated by a medical practitioner in consultation with a paediatric endocrinologist; OR
Must be treated by a medical practitioner in consultation with an endocrinologist specialising in paediatrics.

leuprorelin acetate 30 mg injection: modified release [1] (&) inert substance diluent [1 syringe], 1 pack

10255R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	1373.81	38.30	Lucrin Depot Paediatric 30 mg PDS [VE]

▪ LEUPRORELIN

Authority required (STREAMLINED)
5646
Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

leuprorelin acetate 22.5 mg injection: modified release [1] (&) inert substance diluent [1 syringe], 1 pack

8708H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	1049.93	38.30	Eligard 3 month [TL]

leuprorelin acetate 22.5 mg injection: modified release [1] (&) inert substance diluent [2 mL syringe], 1 pack

8876E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	1049.93	38.30	Lucrin Depot 3 Month PDS [VE]

leuprorelin acetate 30 mg injection: modified release [1] (&) inert substance diluent [1 syringe], 1 pack

8709J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	1373.81	38.30	Eligard 4 month [TL]

leuprorelin acetate 30 mg injection: modified release [1] (&) inert substance diluent [2 mL syringe], 1 pack

8877F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	1373.81	38.30	Lucrin Depot 4 Month PDS [VE]

leuprorelin acetate 45 mg injection: modified release [1] (&) inert substance diluent [1 syringe], 1 pack

10656W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	2021.00	38.30	Lucrin Depot 6-Month [VE]

leuprorelin acetate 45 mg injection: modified release [1] (&) inert substance diluent [1 syringe], 1 pack

8859G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	2021.00	38.30	Eligard 6 month [TL]

leuprorelin acetate 7.5 mg injection: modified release [1] (&) inert substance diluent [1 syringe], 1 pack

8707G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	393.28	38.30	Eligard 1 month [TL]

leuprorelin acetate 7.5 mg injection: modified release [1] (&) inert substance diluent [2 mL syringe], 1 pack

8875D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	393.28	38.30	Lucrin Depot 7.5mg PDS [VE]

▪ LEUPRORELIN

Authority required
Central precocious puberty
Treatment Phase: Initial treatment
Population criteria:
Patient must be aged 10 years or younger (girls) or 11 years or younger (boys), AND
Patient must have had onset of signs or symptoms of central precocious puberty prior to the age of 8 years (girls) or 9 years (boys).
Treatment criteria:
Must be treated by a paediatric endocrinologist; OR
Must be treated by an endocrinologist specialising in paediatrics.
Authority required
Central precocious puberty
Treatment Phase: Initial - grandfather
Clinical criteria:
Patient must have received treatment with a gonadotropin releasing hormone analogue (GnRHa) for this condition prior to 1 May 2015.
Treatment criteria:

Must be treated by a paediatric endocrinologist; OR
Must be treated by an endocrinologist specialising in paediatrics.

leuprorelin acetate 30 mg injection: modified release [1] (&) inert substance diluent [1 syringe], 1 pack

10256T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	1373.81	38.30	Lucrin Depot Paediatric 30 mg PDS [VE]

▪ TRIPTORELIN

Authority required (STREAMLINED)
5646
Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

triptorelin 11.25 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack

9379P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	1049.93	38.30	Diphereline [IS]

triptorelin 22.5 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack

5297T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	2021.00	38.30	Diphereline [IS]

triptorelin 3.75 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack

9378N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	393.28	38.30	Diphereline [IS]

HORMONE ANTAGONISTS AND RELATED AGENTS

Anti-estrogens

▪ TAMOXIFEN

Note This drug is not PBS-subsidised for primary prevention of breast cancer.
Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Breast cancer
Clinical criteria:
The condition must be hormone receptor positive.

tamoxifen 10 mg tablet, 60

2109B NP	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	23.48	24.65	Genox 10 [AF]

▪ TAMOXIFEN

Note This drug is not PBS-subsidised for primary prevention of breast cancer.
Note For item codes 2110C and 1880Y, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.
Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Breast cancer
Clinical criteria:
The condition must be hormone receptor positive.

tamoxifen 20 mg tablet, 30

1880Y NP	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	[B]2.20	*35.27	34.24	[a] Nolvadex-D [AP]

tamoxifen 20 mg tablet, 60

2110C NP	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	33.06	34.23	[a] Genox 20 [AF] [a] Tamosin [QA] [a] Tamoxifen Sandoz [SZ]	[a] GenRx Tamoxifen [GX] [a] Tamoxen 20 mg [EA]

▪ TOREMIFENE

toremifene 60 mg tablet, 30

8216K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	68.56	38.30	Fareston [AS]

Anti-androgens

▪ BICALUTAMIDE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
5729
Metastatic (stage D) carcinoma of the prostate
Clinical criteria:
The treatment must be in combination with GnRH (LH-RH) analogue therapy.

bicalutamide 50 mg tablet, 28

8094B
NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	86.03	38.30	[a] APO-Bicalutamide [TX] [a] Bicalutamide AN [EA] [a] Calutex [QA] [a] Cosudex [AP]	[a] Bicalox [ER] [a] Bicalutamide-GA [ED] [a] Cosamide [AF]

▪ CYPROTERONE

cyproterone acetate 100 mg tablet, 50

8019C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	81.65	38.30	[a] Cyprocur 100 [QA] [a] Cyproterone AN [EA] [a] GenRx Cyproterone Acetate [GX]	[a] Cyprostat-100 [SY] [a] Cyproterone Sandoz [HX] [a] Procur 100 [ED]
		[B]1.80	83.45	38.30	[a] Androcur-100 [BN]	

cyproterone acetate 50 mg tablet, 50

1270W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*101.89	38.30	[a] Cyprocur 50 [QA] [a] Cyprostat [SY] [a] Cyproterone Sandoz [HX] [a] GenRx Cyproterone Acetate [GX]	[a] Cyprone [AF] [a] Cyproterone AN [EA] [a] Cyrotone [ER] [a] Procur [ED]
		[B]2.88	*104.77	38.30	[a] Androcur [BN]	

▪ ENZALUTAMIDE

Note Special Pricing Arrangements apply.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required
Castration resistant metastatic carcinoma of the prostate
Clinical criteria:
The treatment must not be used in combination with chemotherapy, AND
Patient must have failed treatment with docetaxel due to resistance or intolerance; OR
Patient must be unsuitable for docetaxel treatment on the basis of predicted intolerance to docetaxel, AND
Patient must have a WHO performance status of 2 or less, AND
Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, AND
Patient must not have received prior treatment with abiraterone; OR
Patient must have developed intolerance to abiraterone of a severity necessitating permanent treatment withdrawal.

enzalutamide 40 mg capsule, 112

10174L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	3700.17	38.30	Xtandi [LL]

▪ FLUTAMIDE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

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

Authority required (STREAMLINED)

5816

Metastatic (stage D) carcinoma of the prostate

Clinical criteria:

The treatment must be in combination with GnRH (LH-RH) analogue therapy.

flutamide 250 mg tablet, 100

1417N

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	169.70	38.30	Flutamin [AF]

▪ NILUTAMIDE

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

Authority required (STREAMLINED)

5785

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

Clinical criteria:

The treatment must be in combination with GnRH (LH-RH) analogue therapy.

Authority required (STREAMLINED)

5647

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

Clinical criteria:

The treatment must be in conjunction with surgical orchidectomy.

nilutamide 150 mg tablet, 30

8131Y

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	212.71	38.30	Anandron [SW]

Aromatase inhibitors

▪ ANASTROZOLE

Note This drug is not PBS-subsidised for primary prevention of breast cancer.

Note This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

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

Restricted benefit

Breast cancer

Clinical criteria:

The condition must be hormone receptor positive.

anastrozole 1 mg tablet, 30

8179L

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	63.28	38.30	[a] Anastrol [QA] [a] Anastrozole FBM [FO] [a] Anastrozole RBX [RA] [a] APO-Anastrozole [TX] [a] Arimidex [AP] [a] Chem mart Anastrozole [CH] [a] Terry White Chemists Anastrozole [TW]	[a] Anastrozole AN [EA] [a] Anastrozole GH [GQ] [a] Anastrozole Sandoz [SZ] [a] Arianna [AF] [a] Azastrole [ER] [a] Pharmacor Anastrozole 1 [CR]

▪ EXEMESTANE

Restricted benefit

Metastatic (Stage IV) breast cancer

Clinical criteria:

The condition must be hormone receptor positive, AND

The condition must be human epidermal growth factor receptor 2 (HER2) negative, AND

Patient must be receiving PBS-subsidised everolimus concomitantly for this condition.

Population criteria:

Patient must not be pre-menopausal.

exemestane 25 mg tablet, 30

10103R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	87.48	38.30	[a] APO-Exemestane [TX] [a] Exemestane AN [EA] [a] Exemestane GH [GQ] [a] Exemestane Sandoz [SZ]	[a] Exaccord [RA] [a] Exemestane-GA [ED] [a] Exemestane Pfizer [FZ]
			[B]1.70	89.18	38.30	[a] Aromasin [PF]	

▪ EXEMESTANE

Note This drug is not PBS-subsidised for primary prevention of breast cancer.

Note This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years, i.e. a patient who has received 2 years of tamoxifen therapy may only receive 3 years of PBS-subsidised treatment with exemestane.

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

Restricted benefit

Breast cancer

Clinical criteria:

The condition must be hormone receptor positive.

exemestane 25 mg tablet, 30

8506Q NP	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	87.48	38.30	[a] APO-Exemestane [TX] [a] Exemestane AN [EA] [a] Exemestane GH [GQ] [a] Exemestane Sandoz [SZ]	[a] Exaccord [RA] [a] Exemestane-GA [ED] [a] Exemestane Pfizer [FZ]
			[B]1.70	89.18	38.30	[a] Aromasin [PF]	

▪ LETROZOLE

Note This drug is not PBS-subsidised for primary prevention of breast cancer.

Note This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer where the total duration of this drug (or any other aromatase inhibitor) treatment extends beyond 5 years.

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

Restricted benefit

Breast cancer

Clinical criteria:

The condition must be hormone receptor positive.

letrozole 2.5 mg tablet, 30

8245Y NP	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	56.00	38.30	[a] APO-Letrozole [TX] [a] Femara 2.5 mg [NV] [a] Fera [QA] [a] Letrozole AN [EA] [a] Letrozole generichealth [GQ] [a] Letrozole Sandoz [SZ] [a] Pharmacor Letrozole 2.5 [CR]	[a] Chem mart Letrozole [CH] [a] Femolet [AF] [a] Gynotril [ER] [a] Letrozole FBM [FO] [a] Letrozole RBX [RA] [a] Lezole [ED] [a] Terry White Chemists Letrozole [TW]

Other hormone antagonists and related agents

▪ ABIRATERONE

Note Special Pricing Arrangements apply.

Authority required

Castration resistant metastatic carcinoma of the prostate

Clinical criteria:

The treatment must be in combination with prednisone or prednisolone, AND

The treatment must not be used in combination with chemotherapy, AND

Patient must have failed treatment with docetaxel due to resistance or intolerance; OR

Patient must be unsuitable for docetaxel treatment on the basis of predicted intolerance to docetaxel, AND

Patient must have a WHO performance status of 2 or less, AND

Patient must not receive PBS-subsidised abiraterone if progressive disease develops while on abiraterone, AND

Patient must not have received prior treatment with enzalutamide; OR

Patient must have developed intolerance to enzalutamide of a severity necessitating permanent treatment withdrawal.

abiraterone acetate 250 mg tablet, 120

2698B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	3600.41	38.30	Zytiga [JC]

▪ DEGARELIX

Authority required (STREAMLINED)

5646

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

degarelix 80 mg injection [1 vial] (&) inert substance diluent [1 syringe], 1 pack

2784M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	393.28	38.30	Firmagon 80mg [FP]

▪ DEGARELIX

Note No applications for increased maximum quantities and/or repeats will be authorised for the 120 mg powder for injection.

Authority required (STREAMLINED)

5786

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

degarelix 120 mg injection [2 vials] (&) inert substance diluent [2 syringes], 1 pack

2785N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	411.48	38.30	Firmagon 120mg [FP]

▪ IMMUNOSTIMULANTS

IMMUNOSTIMULANTS

Interferons

▪ INTERFERON ALFA-2A

Caution Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Authority required

Myeloproliferative disease with excessive thrombocytosis

interferon alfa-2a 4.5 million units/0.5 mL injection, 0.5 mL syringe

8551C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	5	4	..	*240.43	38.30	Roferon-A [RO]

interferon alfa-2a 6 million units/0.5 mL injection, 0.5 mL syringe

8552D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	5	4	..	*319.08	38.30	Roferon-A [RO]

interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe

8553E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	5	4	..	*476.58	38.30	Roferon-A [RO]

▪ INTERFERON ALFA-2A

Caution Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Authority required

Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy

interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe

8181N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	15	5	..	*476.73	38.30	Roferon-A [RO]

interferon alfa-2a 4.5 million units/0.5 mL injection, 0.5 mL syringe

8182P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	5	5	..	*240.43	38.30	Roferon-A [RO]

interferon alfa-2a 6 million units/0.5 mL injection, 0.5 mL syringe

8183Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	5	5	..	*319.08	38.30	Roferon-A [RO]

interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe

8184R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5	5	..	*476.58	38.30	Roferon-A [RO]

▪ INTERFERON ALFA-2A

Caution Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Authority required

Hairy cell leukaemia

Authority required

Myeloproliferative disease with excessive thrombocytosis

interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe

8180M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
15	4	..	*476.73	38.30	Roferon-A [RO]

▪ INTERFERON ALFA-2B

Caution Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Authority required

Hairy cell leukaemia

interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL cartridge

8572E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	4	..	*570.99	38.30	Intron A Redipen [MK]

▪ INTERFERON ALFA-2B

Caution Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Authority required

Maintenance treatment of multiple myeloma once remission has been achieved with chemotherapy

Authority required

Low grade non-Hodgkin's lymphoma with clinical features suggestive of a poor prognosis, in combination with anthracycline-based chemotherapy

interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL cartridge

8348J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	5	..	*570.99	38.30	Intron A Redipen [MK]

interferon alfa-2b 30 million units/1.2 mL injection, 1.2 mL cartridge

8476D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	5	..	*948.93	38.30	Intron A Redipen [MK]

▪ INTERFERON BETA-1A

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4881

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND

Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, AND

Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required (STREAMLINED)

4887

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, AND

Patient must have previously been issued with an authority prescription for this drug, AND
Patient must not show continuing progression of disability while on treatment with this drug, AND
Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

INTERFERON BETA-1a Injection 44 micrograms (12,000,000 i.u.) in 0.5 mL single dose autoinjector, 12

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8968B	1	5	..	997.89	38.30	Rebif 44 [SG]

interferon beta-1a 132 microgram/1.5 mL (12 million units) injection, 4 x 1.5 mL cartridges

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9332E	1	5	..	997.89	38.30	Rebif 44 [SG]

interferon beta-1a 44 microgram/0.5 mL (12 million units) injection, 12 x 0.5 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8403G	1	5	..	997.89	38.30	Rebif 44 [SG]

interferon beta-1a 6 million units (30 microgram) injection [4 vials] (&) inert substance diluent [4 x 1.1 mL syringes], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8289G	1	5	..	997.89	38.30	Avonex [BD]

interferon beta-1a 6 million units (30 microgram)/0.5 mL injection, 4 x 0.5 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8805K	1	5	..	997.89	38.30	Avonex [BD]

▪ INTERFERON BETA-1B

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)
4881
Multiple sclerosis
Treatment Phase: Initial treatment
Clinical criteria:
The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND
Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, AND
Patient must be ambulatory (without assistance or support).
Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.
Authority required (STREAMLINED)
4887
Multiple sclerosis
Treatment Phase: Continuing treatment
Clinical criteria:
The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, AND
Patient must have previously been issued with an authority prescription for this drug, AND
Patient must not show continuing progression of disability while on treatment with this drug, AND
Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

interferon beta-1b 8 million international units (250 microgram) injection [15 x 250 microgram vials] (&) inert substance diluent [15 x 1.2 mL syringes], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8101J	1	5	..	993.72	38.30	Betaferon [BN]

▪ PEGINTERFERON ALFA-2A (&) RIBAVIRIN

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required
Chronic hepatitis C infection
Clinical criteria:
Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 12 weeks.

Population criteria:

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [140 tablets], 1 pack

10636T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	1686.35	38.30	Pegasys RBV [RO]

peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack

10634Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	1769.43	38.30	Pegasys RBV [RO]

▪ PEGINTERFERON BETA-1A

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4881

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND

Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, AND

Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL injection devices

10212L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	4	..	1049.42	38.30	Plegridy [BD]

peginterferon beta-1a 63 microgram/0.5 mL injection [0.5 mL injection device] (&) peginterferon beta-1a 94 microgram/0.5 mL injection [0.5 mL injection device], 1 pack

10218T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	1049.42	38.30	Plegridy [BD]

▪ PEGINTERFERON BETA-1A

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4887

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, AND

Patient must have previously been issued with an authority prescription for this drug, AND

Patient must not show continuing progression of disability while on treatment with this drug, AND

Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

peginterferon beta-1a 125 microgram/0.5 mL injection, 2 x 0.5 mL injection devices

10220X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	1049.42	38.30	Plegridy [BD]

Other immunostimulants

▪ BACILLUS CALMETTE AND GUERIN-CONNAUGHT STRAIN

Restricted benefit

Carcinoma in situ of the urinary bladder

Bacillus Calmette and Guerin-Connaught strain 660 million colony forming units injection [81 mg vial] (&) inert substance diluent [3 mL vial], 1 pack

1140B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3	1	..	*432.27	38.30	ImmuCyst [SW]

▪ BACILLUS CALMETTE AND GUERIN-TICE STRAIN

Restricted benefit

Primary and relapsing superficial urothelial carcinoma of the bladder

Bacillus Calmette and Guerin-Tice strain 500 million colony forming units injection, 3 vials

1131M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	524.08	38.30	OncoTICE [MK]

▪ GLATIRAMER ACETATE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4881

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, with written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND

Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, AND

Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority required (STREAMLINED)

4887

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis, AND

Patient must have previously been issued with an authority prescription for this drug, AND

Patient must not show continuing progression of disability while on treatment with this drug, AND

Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

glatiramer acetate 20 mg/mL injection, 28 x 1 mL syringes

8726G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1034.36	38.30	Copaxone [TB]

glatiramer acetate 40 mg/mL injection, 12 x 1 mL syringes

10416F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1034.36	38.30	Copaxone [TB]

▪ IMMUNOSUPPRESSANTS

IMMUNOSUPPRESSANTS

Selective immunosuppressants

▪ ABATACEPT

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

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

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

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

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

An adequate response to treatment is defined as:

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

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

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

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

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

If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

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

(1) a completed authority prescription form; and

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

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

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

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

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than

24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD.

However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

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

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

abatacept 125 mg/mL injection, 4 x 1 mL syringes

1221G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1249.83	38.30	Orencia [BQ]

▪ ABATACEPT

Authority required

Severe active rheumatoid arthritis

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

Clinical criteria:

Patient must have severe active rheumatoid arthritis, AND

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

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

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

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

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

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

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

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

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

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

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

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

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

(1) completed authority prescription forms; and

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

(3) a signed patient acknowledgement.

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

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

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

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

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

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

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

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

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

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

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

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

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

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

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to

treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

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

Clinical criteria:

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

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

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

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

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

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

(a) completed authority prescription forms; and

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

Applications for a patient who has received PBS-subsidised treatment with this drugt and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats.

Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 3 repeats.

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

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

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

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

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

An adequate response to treatment is defined as:

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

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

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

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

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

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who

has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the

required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

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

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

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

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

abatacept 125 mg/mL injection, 4 x 1 mL syringes

1220F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1249.83	38.30	Orencia [BQ]

▪ EVEROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority required

Maintenance of renal transplant

Treatment Phase: Maintenance therapy (following initiation and stabilisation of treatment with everolimus)

Clinical criteria:

Patient must have undergone a renal transplant, AND

The treatment must be under the supervision and direction of a transplant unit.

The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit are included in the authority application

Authority required

Maintenance of cardiac transplant

Treatment Phase: Maintenance therapy (following initiation and stabilisation of treatment with everolimus)

Clinical criteria:

Patient must have undergone a cardiac transplant, AND

The treatment must be under the supervision and direction of a transplant unit.

The name of the specialised transplant unit reviewing treatment and the date of the latest review at the specialised transplant unit are included in the authority application

everolimus 1 mg tablet, 60

9352F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	3	..	*1966.71	38.30	Certican [NV]

everolimus 250 microgram tablet, 60

8840G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	258.17	38.30	Certican [NV]

everolimus 500 microgram tablet, 60

8841H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	512.20	38.30	Certican [NV]

everolimus 750 microgram tablet, 60

8842J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	3	..	*1494.17	38.30	Certican [NV]

▪ FINGOLIMOD

Note Special Pricing Arrangements apply.

Authority required

Initial treatment, as monotherapy, of clinically definite relapsing-remitting multiple sclerosis in an ambulatory (without assistance or support) patient who has experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years. The diagnosis must be confirmed by magnetic resonance imaging of the brain and/or spinal cord and the date of the scan included in the authority application, unless the authority application is accompanied by written certification provided by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient. The authority will be limited to the maximum quantity and number of repeats indicated in the schedule

Authority required

Continuing treatment, as monotherapy, of clinically definite relapsing-remitting multiple sclerosis in a patient previously issued with an authority prescription for this drug who does not show continuing progression of disability while on treatment with this drug and who has demonstrated compliance with, and an ability to tolerate, this therapy. Authorities will be limited to the maximum quantity and number of repeats indicated in the schedule

fingolimod 500 microgram capsule, 28

5262Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	2313.49	38.30	Gilenya [NV]

▪ LEFLUNOMIDE

Caution Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

Authority required (STREAMLINED)

5766

Severe active psoriatic arthritis

Clinical criteria:

Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR

Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, AND

The treatment must be initiated by a physician.

leflunomide 10 mg tablet, 30

5449T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	43.08	38.30	[a] Arabloc [AV] [a] Leflunomide APOTEX [GX]	[a] Arava [SW] [a] Leflunomide Sandoz [SZ]

leflunomide 20 mg tablet, 30

5450W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	60.15	38.30	[a] Arabloc [AV] [a] Leflunomide APOTEX [GX]	[a] Arava [SW] [a] Leflunomide Sandoz [SZ]

▪ LEFLUNOMIDE

Caution Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

Authority required (STREAMLINED)

5681

Severe active rheumatoid arthritis

Clinical criteria:

Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR

Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, AND

The treatment must be initiated by a physician.

leflunomide 10 mg tablet, 30

8374R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	43.08	38.30	[a] APO-Leflunomide [TX] [a] Arava [SW] [a] Leflunomide APOTEX [GX] [a] Leflunomide GH [GQ] [a] Lunava 10 [ZP]	[a] Arabloc [AV] [a] Leflunomide AN [EA] [a] Leflunomide-GA [ED] [a] Leflunomide Sandoz [SZ]

leflunomide 20 mg tablet, 30

8375T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	60.15	38.30	[a] APO-Leflunomide [TX] [a] Arava [SW] [a] Leflunomide APOTEX [GX] [a] Leflunomide GH [GQ] [a] Lunava 20 [ZP]	[a] Arabloc [AV] [a] Leflunomide AN [EA] [a] Leflunomide-GA [ED] [a] Leflunomide Sandoz [SZ]

▪ MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

mycophenolate 180 mg tablet: enteric, 120

2150E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	102.66	38.30	Myfortic [NV]

mycophenolate 360 mg tablet: enteric, 120

2193K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	195.04	38.30	Myfortic [NV]

mycophenolate mofetil 1 g/5 mL oral liquid: powder for, 165 mL

8651H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	#278.87	38.30	CellCept [RO]

mycophenolate mofetil 500 mg tablet, 50

8650G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	5	..	*242.76	38.30	[a] APO-Mycophenolate [TX] [a] Ceptolate [AF] [a] Mycophenolate Sandoz [SZ]	[a] CellCept [RO] [a] Mycophenolate AN [EA] [a] Pharmacor Mycophenolate 500 [CR]

▪ MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Note For item codes 8649F and 1836P, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution.

mycophenolate Capsule 250 mg, 50

1836P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
6	5	..	*242.85	38.30	[a] Ceptolate [AF]

mycophenolate mofetil 250 mg capsule, 100

8649F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	5	..	*242.82	38.30	[a] APO-Mycophenolate [TX] [a] Mycophenolate Sandoz [SZ]	[a] CellCept [RO] [a] Pharmacor Mycophenolate 250 [CR]

▪ SIROLIMUS

Caution Careful monitoring of patients is mandatory.

sirolimus 1 mg tablet, 100

8724E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	768.81	38.30	Rapamune [PF]

sirolimus 1 mg/mL oral liquid, 60 mL

8725F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	3	..	498.88	38.30	Rapamune [PF]

sirolimus 2 mg tablet, 100

8833X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	1498.95	38.30	Rapamune [PF]

sirolimus 500 microgram tablet, 100

8984W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	386.48	38.30	Rapamune [PF]

▪ TERIFLUNOMIDE

Caution Teriflunomide is a category X drug and must not be given to pregnant women or women of childbearing potential who are not currently using reliable contraception.

Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND

The treatment must be as monotherapy, AND

Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years; OR

Patient must have been receiving treatment with this drug prior to 1 December 2013, AND

Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.

Authority required

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND

The treatment must be as monotherapy, AND

Patient must have previously been issued with an authority prescription for this drug, AND

Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.

teriflunomide 14 mg tablet, 28

2898M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	1836.59	38.30	Aubagio [GZ]

▪ TOFACITINIB

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval should be forwarded to:
Department of Human Services

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

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

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

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

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

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

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

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

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

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

(a) Initial treatment.

Applications for initial treatment should be made where:

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

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

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

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

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

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

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

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

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

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

Abatacept patients:

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

Rituximab patients:

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

(b) Continuing treatment.

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

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

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

Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

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

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

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

An adequate response to treatment is defined as:

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

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

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

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

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

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

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

(1) a completed authority prescription form; and

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

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

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

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

tofacitinib 5 mg tablet, 56

10511F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1763.57	38.30	Xeljanz [PF]

▪ TOFACITINIB

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the

baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

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

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

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

Clinical criteria:

Patient must have severe active rheumatoid arthritis, AND

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

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

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

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

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

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

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

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

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

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

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

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

(1) a completed authority prescription form; and

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

(3) a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility

for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

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

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

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

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

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

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

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

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

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

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

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

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe this drug may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe this drug should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

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

Clinical criteria:

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

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

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

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

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

(a) a completed authority prescription form and

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

Application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

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

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

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

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

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

An adequate response to treatment is defined as:

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

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

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

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

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

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (Grandfather patients)

Clinical criteria:

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

Patient must have been receiving treatment with this drug for this condition prior to 1 October 2015, AND

Patient must be receiving treatment with this drug for this condition at the time of application, AND

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

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

(a) a completed authority prescription form; and

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

(c) a signed patient acknowledgement.

All applications for treatment with this drug for this condition under this restriction must include baseline joint count and ESR and/or CRP as determined at the completion of a 6 month intensive DMARD trial but prior to ceasing DMARD therapy.

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

A patient may qualify for PBS-subsidised treatment under this restriction once only.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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tofacitinib 5 mg tablet, 56

10517M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	1763.57	38.30	Xeljanz [PF]

Tumor necrosis factor alpha (TNF-) inhibitors

▪ ADALIMUMAB

Note Special Pricing Arrangements apply.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authority approval for sufficient therapy to complete the balance of supply should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time.
For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.
From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab.
Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.
A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.
A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2015.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to theDepartment of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.
For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.
(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient with severe disease may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).
A patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PCDAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.
Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.
A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply for paediatric patient

Clinical criteria:

Patient must have received insufficient therapy with this drug under Initial 1 (new patient or patient recommencing treatment after break of more than 5 years) or Initial 2 (change or recommencement of treatment after a break of less than 5 years) or Initial 3 (grandfathered patients) or Continuing treatment to complete the maximum duration of treatment specified in the relevant treatment phase, AND

The treatment must provide no more than the balance of up to 16 weeks of therapy (new patients or change/re-commencement patients; Initial 1 or Initial 2) or 24 weeks of therapy (Continuing patients or Grandfathered patients).

Treatment criteria:

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician or a specialist paediatric gastroenterologist; OR

Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes

10422M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	1679.21	38.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

10400J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	1679.21	38.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

10399H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	1679.21	38.30	Humira [VE]

▪ ADALIMUMAB

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND

Patient must have demonstrated an adequate response to treatment with adalimumab, AND

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

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

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

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

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

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

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

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

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

(1) a completed authority prescription form; and

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

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

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

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:

Patient must have received insufficient adalimumab therapy under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

5284D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1679.21	38.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

5283C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1679.21	38.30	Humira [VE]

▪ ADALIMUMAB

Note Any queries concerning the arrangements to prescribe adalimumab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.
Written applications for authority to prescribe adalimumab should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.
From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.
A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.
A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course

was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

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

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

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

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

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

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

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

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

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

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

Authority required

Initial 1

Initial treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with adalimumab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has an externally draining enterocutaneous or rectovaginal fistula; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

Authority required

Initial 2

Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with adalimumab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and

(c) has not failed PBS-subsidised therapy with adalimumab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the time frames specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum of 16 weeks treatment will be authorised under this criterion.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats. Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

8965W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	1679.21	38.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

8963R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	1679.21	38.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges

8962Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	4792.37	38.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL syringes

8961P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	4792.37	38.30	Humira [VE]

▪ ADALIMUMAB

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe adalimumab should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

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

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

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

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

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

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

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

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

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

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

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

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

Authority required

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with adalimumab.

Initial PBS-subsidised supply for continuing treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

(a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with adalimumab prior to 4 November 2010; and

(b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with adalimumab; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) is receiving treatment with adalimumab at the time of application; and

(e) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to adalimumab treatment is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with adalimumab.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

A maximum of 24 weeks treatment will be approved under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

Authority required

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with adalimumab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with adalimumab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, an assessment of the patient's response must be made following a minimum of 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with adalimumab.

Patients are eligible to receive continuing adalimumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

8966X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1679.21	38.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

8964T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1679.21	38.30	Humira [VE]

▪ ADALIMUMAB

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

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

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

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

An adequate response to treatment is defined as:

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

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

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

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

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

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

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

(1) a completed authority prescription form; and

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

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

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

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

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab,

etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major

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

Note No increase in the maximum quantity or number of units may be authorised.
No increase in the maximum number of repeats may be authorised.
Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.
Special Pricing Arrangements apply

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

9100Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1679.21	38.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

8741C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1679.21	38.30	Humira [VE]

▪ ADALIMUMAB

Note No applications for increased maximum quantities will be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Special Pricing Arrangements apply.

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab).
Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.
From 1 August 2015, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised TNF-alfa antagonist or vedolizumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist or vedolizumab while they continue to show a response to therapy.
A patient who received PBS-subsidised TNF-alfa antagonist or vedolizumab treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist or vedolizumab more than twice.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist or vedolizumab treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist or vedolizumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised TNF-alfa antagonist or vedolizumab therapy after 1 August 2015.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised therapy with TNF-alfa antagonist or vedolizumab in this treatment cycle and wishes to commence such therapy (new patients); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy or vedolizumab and wishes to trial an alternate agent (recommencement) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist or vedolizumab following a break in PBS-subsidised therapy with that agent (change or re-commencement).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab and 14 weeks of therapy for vedolizumab.
From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.
For second and subsequent courses of PBS-subsidised TNF-alfa antagonist or vedolizumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific TNF-alfa antagonist or vedolizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist or vedolizumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist or vedolizumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist or vedolizumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist or vedolizumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.
A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will

be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe Crohn disease, AND

Patient must have previously been issued with an authority prescription for this drug for this condition, AND

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

Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR

Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient dose. Up to a maximum of 5 repeats will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

9191R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1679.21	38.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9189P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1679.21	38.30	Humira [VE]

▪ ADALIMUMAB

Note Special Pricing Arrangements apply.

Note No applications for increased maximum quantities will be authorised.

Note No increase in the maximum number of repeats may be authorised.

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time.
For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.
From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab.
Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.
A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.
A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2015.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to theDepartment of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.
For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient with severe disease may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn

disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).
A patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PCDAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.
Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.
A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment (new paediatric patient) of Crohn disease in a paediatric patient assessed by PCDAI (Initial 1)

Clinical criteria:

Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, AND

Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR

Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, AND

Patient must have, at the time of application, disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment and which is no more than 1 month old at the time of application.

Population criteria:

Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician; OR

Must be treated by a specialist paediatric gastroenterologist.

Applications for authorisation of initial treatment must be in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition; and

(iii) the signed patient or guardian acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Human Services website (www.humanservices.gov.au).

A maximum quantity and number of repeats to provide for an initial 16 week course of this drug consisting of a 160 mg dose at week 0, 80 mg dose at week 2 and 40 mg dose at weeks 4, 6, 8, 10, 12 and 14 for patients 40 kg or greater (for patients 40 kg or less, the course is a 80 mg dose at week 0, 40 mg dose at week 2 and a 20 mg dose at weeks 4, 6, 8, 10, 12 and 14) will be authorised.

Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater: one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg: one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these time-frames, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Authority required

Severe Crohn disease

Treatment Phase: Change or re-commencement of treatment of Crohn disease in a paediatric patient assessed by PCDAI (Initial 2)

Clinical criteria:

Patient must have a documented history of severe Crohn disease, AND

Patient must in this treatment cycle, have received prior PBS-subsidised treatment with this drug for this condition; OR

Patient must in this treatment cycle, have received prior PBS-subsidised treatment with this drug for this condition; OR

Patient must in this treatment cycle, have received prior PBS-subsidised treatment with infliximab for this condition and have a current PCDAI score of 40 or greater; OR

Patient must in this treatment cycle, have received prior PBS-subsidised treatment with infliximab for this condition and have a current PCDAI score of 40 or greater, AND

Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

Population criteria:

Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician; OR

Must be treated by a specialist paediatric gastroenterologist.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Applications for authorisation of initial treatment must be in writing and must include:

(a) two completed authority prescription form; and

(b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and

(ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. For patients weighing 40 kg or greater: one prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats. For patients weighing less than 40 kg: one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

If fewer than 2 repeats (for patients 40 kg or greater) or 3 repeats (for patients less than 40 kg) are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these time-frames, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes

10389T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	1679.21	38.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

10413C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	1679.21	38.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

10419J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	1679.21	38.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges

10397F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	4792.37	38.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL syringes

10404N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	4792.37	38.30	Humira [VE]

▪ ADALIMUMAB

Note Special Pricing Arrangements apply.

Note No applications for increased maximum quantities will be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time.
For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.
From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab.

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.
A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.
A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2015.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to theDepartment of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.
For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient with severe disease may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).
A patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PCDAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment

applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.
Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.
A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

Authority required

Severe Crohn disease

Treatment Phase: Initial PBS-subsidised treatment of Crohn disease in a paediatric patient who has previously received non-PBS-subsidised therapy with this drug (Initial 3 - Grandfather)

Clinical criteria:

Patient must have been receiving treatment with this drug prior to 1 August 2015, AND

Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, AND

Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR

Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, AND

Patient must have had disease severity considered to be severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 40 preferably whilst still on prior conventional treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment, AND

Patient must have demonstrated an adequate response to treatment with this drug as defined as a reduction in PCDAI Score by at least 15 points as compared to baseline and a total of PCDAI score of 40 points or less with the PCDAI assessment being no more than 1 month old at the time of application.

Population criteria:

Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician or a specialist paediatric gastroenterologist; OR

Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:

(i) the completed current and baseline Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet;

(ii) the date of commencement of this drug; and

(iii) the signed patient or guardian acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

The patient's current PCDAI assessment must be no more than 1 month old at the time of application. The baseline PCDAI assessment must be from immediately prior to commencing treatment with this drug.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

A maximum of 24 weeks treatment will be approved under this criterion.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction.

Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Authority required

Severe Crohn disease

Treatment Phase: Continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

Clinical criteria:

Patient must have a documented history of severe Crohn disease, AND

Patient must have previously been issued with an authority prescription for this drug for this condition, AND

Patient must have demonstrated an adequate response to treatment with this drug as defined as a reduction in PCDAI Score by at least 15 points as compared to baseline and a total of PCDAI score of 40 points or less with the PCDAI assessment being no more than 1 month old at the time of application.

Population criteria:

Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician; OR

Must be treated by a specialist paediatric gastroenterologist.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:

(i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with adalimumab, a PCDAI assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.

Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction.

adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes

10396E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1679.21	38.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

10420K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1679.21	38.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

10412B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1679.21	38.30	Humira [VE]

▪ ADALIMUMAB

Authority required

Severe active juvenile idiopathic arthritis

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

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND

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

Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle, AND

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

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

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

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

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

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

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

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

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

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

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

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

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

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

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

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

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

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

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

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

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

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

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

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

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

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

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

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

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.

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

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

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

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

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, AND

Patient must not have failed PBS-subsidised therapy with adalimumab for this condition in the current treatment cycle, AND

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

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

(1) a completed authority prescription form; and

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

Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

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

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

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

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

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

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

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

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

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

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

Clinical criteria:

Patient must have received insufficient adalimumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient adalimumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5282B	1	3	..	1679.21	38.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5281Y	1	3	..	1679.21	38.30	Humira [VE]

▪ ADALIMUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis, AND

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

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

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

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

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.
Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.
From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.
A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the

baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis, AND

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

9104E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1679.21	38.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9078T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1679.21	38.30	Humira [VE]

▪ ADALIMUMAB

Authority required

Severe active rheumatoid arthritis

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

Clinical criteria:

Patient must have severe active rheumatoid arthritis, AND

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

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

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

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

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine,

leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

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

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

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

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

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

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

(1) a completed authority prescription form; and

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

(3) a signed patient acknowledgement.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

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

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

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

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note No increase in the maximum quantity or number of units may be authorised.
No increase in the maximum number of repeats may be authorised.
Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.
Special Pricing Arrangements apply

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) a completed authority prescription form and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the

commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note No increase in the maximum quantity or number of units may be authorised.

No increase in the maximum number of repeats may be authorised.

Applications for treatment with this drug where the dosing frequency exceeds 40 mg per fortnight will not be approved.

Special Pricing Arrangements apply

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

9099X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1679.21	38.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

8737W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1679.21	38.30	Humira [VE]

▪ ADALIMUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis, AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND

Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab for adult patients with severe active psoriatic arthritis.
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.
Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab only.
Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.
Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.
Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.
Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of

therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.
Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
Grandfather patients - ustekinumab only.
For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

9102C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	1679.21	38.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9034L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	1679.21	38.30	Humira [VE]

▪ ADALIMUMAB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, AND

Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab or infliximab in this treatment cycle, AND

Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, AND

Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

Authority required

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis, AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, AND

Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, AND

Patient must be eligible to receive further bDMARD therapy.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.
Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.
From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.
A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

Clinical criteria:

Patient must have active, or a documented history of active, ankylosing spondylitis, AND

Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

9103D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1679.21	38.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9077R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1679.21	38.30	Humira [VE]

▪ ADALIMUMAB

Note No applications for increased maximum quantities will be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Special Pricing Arrangements apply.

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab).
Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.
From 1 August 2015, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised TNF-alfa antagonist or vedolizumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist or vedolizumab while they continue to show a response to therapy.
A patient who received PBS-subsidised TNF-alfa antagonist or vedolizumab treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist or vedolizumab more than twice.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist or vedolizumab treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist or vedolizumab under the new treatment cycle.
A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised TNF-alfa antagonist or vedolizumab therapy after 1 August 2015.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised therapy with TNF-alfa antagonist or vedolizumab in this treatment cycle and wishes to commence such therapy (new patients); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy or vedolizumab and wishes to trial an alternate agent (recommencement) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist or vedolizumab following a break in PBS-subsidised therapy with that agent (change or re-commencement).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab and 14 weeks of therapy for vedolizumab.
From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.
For second and subsequent courses of PBS-subsidised TNF-alfa antagonist or vedolizumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second

prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist or vedolizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist or vedolizumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist or vedolizumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist or vedolizumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist or vedolizumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.

A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment (new patient - initial 1)

Clinical criteria:

Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, AND

Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR

Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, AND

Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR

Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR

Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug, AND

Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR

Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, AND

Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR

Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR

Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment with adalimumab may be requested by telephone by contacting the Department of Human Services.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial 16 week course of this drug will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

Clinical criteria:

Patient must have a documented history of severe Crohn disease, AND

Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, AND

Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity and number of repeats to provide for an initial 16 week course of this drug will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the initial dose (i.e. the initial infusion regimen at weeks 0 and 2); OR

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, AND

The treatment must provide no more than the balance of up to 2 doses (new patients) or 5 repeats (Continuing treatment).

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Authority approval for sufficient therapy to complete a maximum of 2 initial doses or 5 repeats may be requested by telephone by contacting the Department of Human Services

Note No increase in the maximum quantity or number of units may be authorised.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

9190Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	1679.21	38.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9188N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	1679.21	38.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges

9187M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	4792.37	38.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 6 x 0.8 mL syringes

9186L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	4792.37	38.30	Humira [VE]

▪ ADALIMUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe active psoriatic arthritis, AND

Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, AND

Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, AND

Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR

Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis, AND

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, AND

Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or ustekinumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or

(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

9101B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1679.21	38.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9033K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1679.21	38.30	Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, secukinumab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, secukinumab and ustekinumab only.
Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.
Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.
Patients must be assessed for response to each course of treatment according to the criteria included in the relevant

continuing treatment restriction.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.
Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Application for approval for initial treatment.
Applications for a course of initial treatment should be made in the following situations:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
(iii) patients who wish to recommence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab, etanercept and secukinumab, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.
Grandfather patients (secukinumab only).
Applications for patients who commenced treatment with secukinumab for chronic plaque psoriasis prior to 1 September 2015 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Application for continuing treatment.
Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.
For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
(4) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.
(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction

and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND

Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND

Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, AND

The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to

Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

9428F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1679.21	38.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9427E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1679.21	38.30	Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, secukinumab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, secukinumab and ustekinumab only.
Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.
Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.
Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.
Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Application for approval for initial treatment.
Applications for a course of initial treatment should be made in the following situations:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
(iii) patients who wish to recommence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab, etanercept and secukinumab, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.
Grandfather patients (secukinumab only).
Applications for patients who commenced treatment with secukinumab for chronic plaque psoriasis prior to 1 September 2015 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the

Department of Human Services on 1800 700 270 to discuss.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Application for continuing treatment.
Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.
For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
(4) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.
(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, AND

Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, AND

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, AND

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, AND

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, AND

Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, AND

Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, AND

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, AND

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, AND

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, AND

Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment) restriction to complete 16 weeks treatment, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

9426D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	4	..	1679.21	38.30	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9425C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	4	..	1679.21	38.30	Humira [VE]

▪ CERTOLIZUMAB PEGOL

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis, AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND

Patient must not have not failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times., AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction..

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the

baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND

Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction..

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) a completed authority prescription form and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate,

where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 18 to 20 weeks treatment, depending on the dosage regimen, AND

The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 18-20 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 18-20 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have demonstrated an adequate response to treatment with this drug, AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD

treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before

swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

3425G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1409.10	38.30	Cimzia [UC]

▪ CERTOLIZUMAB PEGOL

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, AND

Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab or infliximab in this treatment cycle, AND

Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, AND

Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 18 to 20 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

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Authority required

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis, AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, AND

Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, AND

Patient must be eligible to receive further bDMARD therapy.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 18 to 20 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.

Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.

From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

Clinical criteria:

Patient must have active, or a documented history of active, ankylosing spondylitis, AND

Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 18 to 20 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 18 to 20 weeks treatment, AND

The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

Note Authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis, AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND

Patient must have demonstrated an adequate response to treatment with this drug.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5

years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.
Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.
From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.
A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis, AND

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

10137M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1409.10	38.30	Cimzia [UC]

▪ CERTOLIZUMAB PEGOL

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe active psoriatic arthritis, AND

Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, AND

Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, AND

Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR

Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, AND

Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis, AND

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, AND

Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, AND

Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or ustekinumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab for adult patients with severe active psoriatic arthritis.
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.
Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab only.
Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.
Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.
Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.
Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.
Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab only.
For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 18 to 20 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 18 to 20 weeks treatment, AND

The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 18 to 20 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826

GPO Box 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis, AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND

Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab for adult patients with severe active psoriatic arthritis.
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.
Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab only.
Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.
Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was

granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.
Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.
Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.
Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
Grandfather patients - ustekinumab only.
For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of

at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

certolizumab pegol 200 mg/mL injection, 2 x 1 mL syringes

10238W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1409.10	38.30	Cimzia [UC]

▪ ETANERCEPT

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND

Patient must have demonstrated an adequate response to treatment with etanercept, AND

Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-

bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:

Patient must have received insufficient etanercept therapy under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

3450N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1679.22	38.30	Enbrel [PF]

ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

3449M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1679.22	38.30	Enbrel [PF]

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

3448L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*1679.21	38.30	Enbrel [PF]

▪ ETANERCEPT

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have demonstrated an adequate response to treatment with this drug, AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be

provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

9460X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1679.22	38.30	Enbrel [PF]

ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

9090K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1679.22	38.30	Enbrel [PF]

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

8638P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*1679.21	38.30	Enbrel [PF]

▪ ETANERCEPT

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR

Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle, AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i)

azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, AND

Patient must not have failed PBS-subsidised therapy with etanercept for this condition in the current treatment cycle, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than

24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

Clinical criteria:

Patient must have received insufficient etanercept therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient etanercept therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

3447K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	1679.22	38.30	Enbrel [PF]

ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

3446J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	1679.22	38.30	Enbrel [PF]

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

3445H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	3	..	*1679.21	38.30	Enbrel [PF]

▪ ETANERCEPT

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis, AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND

Patient must have demonstrated an adequate response to treatment with this drug.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.
Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.
From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.
A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have

received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis, AND

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

9456Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1679.22	38.30	Enbrel [PF]

ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

9086F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1679.22	38.30	Enbrel [PF]

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

8779C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*1679.21	38.30	Enbrel [PF]

▪ ETANERCEPT

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis, AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND

Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological

disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the

dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

9459W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1679.22	38.30	Enbrel [PF]

ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

9089J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1679.22	38.30	Enbrel [PF]

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

8637N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	3	..	*1679.21	38.30	Enbrel [PF]

▪ ETANERCEPT

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis, AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND

Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab for adult patients with severe active psoriatic arthritis.
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.
Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab only.
Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.
Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.
Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.
Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.
Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
Grandfather patients - ustekinumab only.

For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

9458T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1679.22	38.30	Enbrel [PF]

ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

9088H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	1679.22	38.30	Enbrel [PF]

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

9036N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*1679.21	38.30	Enbrel [PF]

▪ ETANERCEPT

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, AND

Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab or infliximab in this treatment cycle, AND

Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, AND

Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

Authority required

Ankylosing spondylitis
Treatment Phase: Initial 2 (change or recommencement for all patients)
Clinical criteria:
Patient must have a documented history of active ankylosing spondylitis, AND
Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, AND
Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, AND
Patient must be eligible to receive further bDMARD therapy.
Population criteria:
Patient must be an adult.
Treatment criteria:
Must be treated by a rheumatologist.
Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.
Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.
A maximum of 16 weeks of treatment with this drug will be approved under this criterion.
Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.
Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.
From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.
A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

Clinical criteria:

Patient must have active, or a documented history of active, ankylosing spondylitis, AND

Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

9455P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	1679.22	38.30	Enbrel [PF]

ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

9085E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	1679.22	38.30	Enbrel [PF]

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

8778B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	3	..	*1679.21	38.30	Enbrel [PF]

▪ ETANERCEPT

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe active psoriatic arthritis, AND

Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, AND

Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, AND

Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR

Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis, AND

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, AND

Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or ustekinumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.
Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab only.
Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.
Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.
Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.
Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.
Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
Grandfather patients - ustekinumab only.
For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

9457R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1679.22	38.30	Enbrel [PF]

ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

9087G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1679.22	38.30	Enbrel [PF]

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

9035M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	3	..	*1679.21	38.30	Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, secukinumab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, secukinumab and ustekinumab only.
Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.
Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.
Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Application for approval for initial treatment.
Applications for a course of initial treatment should be made in the following situations:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
(iii) patients who wish to recommence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab, etanercept and secukinumab, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.
Grandfather patients (secukinumab only).
Applications for patients who commenced treatment with secukinumab for chronic plaque psoriasis prior to 1 September 2015 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Application for continuing treatment.
Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.
For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
(4) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.
(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised

biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND

Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND

Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, AND

The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to

Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

9462B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	1679.22	38.30	Enbrel [PF]

ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

9431J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	1679.22	38.30	Enbrel [PF]

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

9429G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*1679.21	38.30	Enbrel [PF]

▪ ETANERCEPT

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, secukinumab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iii) patients who wish to recommence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab, etanercept and secukinumab, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

Grandfather patients (secukinumab only).

Applications for patients who commenced treatment with secukinumab for chronic plaque psoriasis prior to 1 September 2015 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of

treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Application for continuing treatment.
Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.
For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
(4) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.
(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, AND

Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, AND

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, AND

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, AND

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, AND

Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, AND

Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, AND

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, AND

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, AND

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, AND

Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment) restriction to complete 16 weeks treatment, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

9461Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1679.22	38.30	Enbrel [PF]

ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

9091L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	1679.22	38.30	Enbrel [PF]

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

9037P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	3	..	*1679.21	38.30	Enbrel [PF]

▪ ETANERCEPT

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment (whole body)

Clinical criteria:

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate, AND

Patient must have lesions present for at least 6 months from the time of initial diagnosis, AND

Patient must not have received any prior PBS-subsidised treatment with etanercept for this condition; OR

Patient must not have received any PBS-subsidised treatment with etanercept for this condition for at least 12 months, AND

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, AND

Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Population criteria:

Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Treatment criteria:

Must be treated by a dermatologist.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the parent or authorised guardian signed patient and prescriber acknowledgements.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

Note Details of acceptable toxicities including severity, associated with phototherapy, methotrexate and acitretin, can be found on the Department of Human Services website at www.humanservices.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment or Re-treatment (Whole body) - balance of first supply

Clinical criteria:

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate, AND

Patient must have received insufficient therapy under the Initial treatment (whole body) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment; OR

Patient must have received insufficient therapy under the Re-treatment (whole body) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment or Re-treatment (Whole body) - completion of course

Clinical criteria:

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate, AND

Patient must have received 16 weeks treatment under the Initial treatment (whole body) restriction for severe chronic plaque psoriasis; OR

Patient must have received 16 weeks treatment under the Re-treatment (whole body) restriction for severe chronic plaque psoriasis, AND

Patient must have demonstrated an adequate response to treatment, AND

Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

Treatment criteria:

Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, when compared with the pre-etanercept treatment baseline value.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of assessment of the patient's condition.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

A PASI assessment of the patient's response to the initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for a further 8 weeks of treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their initial 16 week treatment course to ensure continuity of treatment for those patients who meet the eligibility criterion for a further 8 weeks of PBS-subsidised etanercept treatment.

Note In circumstances where it is not possible to submit a response assessment after 12 weeks of treatment, please call the Department of Human Services on 1800 700 270 to discuss.

Note The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Treatment Phase: Re-treatment (Whole body)

Clinical criteria:

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate, AND

Patient must have a documented history of severe chronic plaque psoriasis of the whole body, AND

Patient must have received prior PBS-subsidised treatment with etanercept for this condition in the past 12 months, AND

Patient must have demonstrated a response to etanercept and experienced a disease flare; OR

Patient must not have failed more than once to achieve an adequate response with etanercept, AND

Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a dermatologist.

A patient is eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior etanercept treatment, including date ceased.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment (Face, hand, foot)

Clinical criteria:

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate, AND

Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis, AND

Patient must not have received any prior PBS-subsidised treatment with etanercept for this condition; OR

Patient must not have received any PBS-subsidised treatment with etanercept for this condition for at least 12 months, AND

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; and/or (iii)acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, AND

Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Population criteria:

Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Treatment criteria:

Must be treated by a dermatologist.

Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application.

Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and face, hand, foot area diagrams including the dates of assessment of the patient's condition

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the parent or authorised guardian signed patient and prescriber acknowledgements.

Where a patient has had a 12 month treatment break, the length of the break is measured from the date the most recent treatment was stopped to the date of the application to re-commence treatment.

Note Details of acceptable toxicities including severity, associated with phototherapy, methotrexate and acitretin, can be found on the Department of Human Services website at www.humanservices.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment of Re-treatment (Face, hand, foot) - balance of first supply

Clinical criteria:

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate, AND

Patient must have received insufficient therapy under the Initial treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment; OR

Patient must have received insufficient therapy under the Re-treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment or Re-treatment (Face, hand, foot) - completion of course

Clinical criteria:

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate, AND

Patient must have received 16 weeks treatment under the Initial treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis; OR

Patient must have received 16 weeks treatment under the Re-treatment (Face, hand, foot) restriction for severe chronic plaque psoriasis, AND

Patient must have demonstrated an adequate response to treatment, AND

Patient must not receive more than 8 weeks of treatment with etanercept under this restriction.

Treatment criteria:

Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of assessment of the patient's condition.

The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

A PASI assessment of the patient's response to the initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for a further 8 weeks of treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their initial 16 week treatment course to ensure continuity of treatment for those patients who meet the eligibility criterion for a further 8 weeks of PBS-subsidised etanercept treatment.

Note In circumstances where it is not possible to submit a response assessment after 12 weeks of treatment, please call the Department of Human Services on 1800 700 270 to discuss.

Note The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

TREATMENT OF PATIENTS UNDER 18 YEARS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing of etanercept under the Pharmaceutical Benefits Scheme (PBS) for patients under 18 years with severe chronic plaque psoriasis.

Applications for treatment of this condition will be limited to provide patients with a maximum of 24 weeks of therapy per course of treatment. A maximum of 16 weeks treatment with etanercept will be authorised for the primary application. The balance, a further 8 weeks treatment, will be authorised if the submitted Psoriasis Area and Severity Index (PASI) assessment demonstrates an adequate response to treatment. Where fewer than 3 repeats are requested at the time of the authority application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone.

Once a patient has failed to respond to treatment 2 times, they must have, at a minimum, a 12 month break. The length of a treatment break is measured from the date the most recent treatment was stopped to the date of the first application for initial treatment.

There are separate restrictions for treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made for patients who have received no prior PBS-subsidised biological treatment and wish to commence such therapy.

(2) Applications for approval for re-treatment.

Applications for re-treatment with etanercept should be made in the following situations:

(i) a patient who has received prior PBS-subsidised etanercept and experiences a disease flare, and wishes to start a second or subsequent treatment course with etanercept following a break of less than 12 months in PBS-subsidised therapy; or

(ii) a patient who has received and failed to respond to prior PBS-subsidised etanercept and wishes to start a second or subsequent treatment course following a break of less than 12 months in PBS-subsidised therapy.

For psoriasis affecting the whole body:

Patients are eligible for re-treatment due to disease flare if there is a 50% or greater change in the patients PASI score or the patient has a current PASI score of greater than 15, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

For psoriasis affecting the face, hand or foot:

Patients are eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the three subscores are rated severe to very severe; OR

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

(3) Applications for approval for completion of a course

Applications for a further 8 weeks of treatment to allow for completion of 24 weeks of therapy should be submitted with a PASI assessment.

The PASI assessment must be conducted after at least 12 weeks of treatment.

This assessment must be submitted to Department of Human Services (the Department) within 1 month of the completion of 12 weeks of treatment. Where a response assessment is not undertaken and submitted to the Department within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department on 1800 700 270 to discuss.

(4) Baseline measurements to determine response.

The Department will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for etanercept. However, prescribers may provide new baseline measurements any time that an initial or re-treatment authority is submitted and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.

(5) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.

A patient who wishes to start a second or subsequent treatment course with etanercept following a break in PBS-subsidised etanercept therapy of at least 12 months , must requalify for treatment under the initial treatment restriction. The most recent PASI assessment must be no more than 1 month old at the time of application.

Severe chronic plaque psoriasis

Treatment Phase: Re-treatment (Face, hand, foot)

Clinical criteria:

The treatment must be as systemic monotherapy; OR

The treatment must be in combination with methotrexate, AND

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, AND

Patient must have received prior PBS-subsidised treatment with etanercept for this condition in the past 12 months, AND

Patient must have demonstrated a response to etanercept and experienced a disease flare; OR

Patient must not have failed more than once to achieve an adequate response with etanercept, AND

Patient must not receive more than 16 weeks of treatment with etanercept under this restriction.

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a dermatologist.

A patient is eligible for re-treatment due to disease flare if:

(i) all subscores are rated moderate to severe or 2 of the 3 subscores are rated severe to very severe; or

(ii) the skin area affected is a 50% or greater change or the area affected is 30% or more of the face, palm of a hand or sole of a foot, compared to the most recent response assessment following cessation of the most recent 24 weeks of PBS-subsidised etanercept.

The authority application must be made in writing and must include :

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis in Patients Less Than 18 Years PBS Authority Application - Supporting Information which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area digrams including the dates of assessment of the patient's condition; and

(ii) details of prior etanercept treatment, including date ceased.

Where a patient has had a treatment break the length of the break is measured from the date the most recent treatment was stopped to the date of the application for further treatment.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1964J	1	3	..	1679.22	38.30	Enbrel [PF]

ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1963H	1	3	..	1679.22	38.30	Enbrel [PF]

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1954W	2	3	..	*1679.21	38.30	Enbrel [PF]

▪ GOLIMUMAB

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have demonstrated an adequate response to treatment with this drug, AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

All applications for continuing treatment with golimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the

application is the first application for continuing treatment with golimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with golimumab.

If a patient fails to demonstrate a response to treatment with golimumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3428K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1481.56	38.30	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3429L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1481.56	38.30	Simponi [JC]

▪ GOLIMUMAB

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis, AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND

Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

Patient must not receive more than 16 weeks of treatment under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A

patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the

relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months)

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND

Patient must not receive more than 16 weeks of treatment under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) a completed authority prescription form and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3426H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	1481.56	38.30	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3427J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	..	1481.56	38.30	Simponi [JC]

▪ GOLIMUMAB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required
Ankylosing spondylitis
Treatment Phase: Continuing treatment
Clinical criteria:
Patient must have a documented history of active ankylosing spondylitis, AND
Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND
Patient must have demonstrated an adequate response to treatment with this drug.
Population criteria:
Patient must be an adult.
Treatment criteria:
Must be treated by a rheumatologist.
An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:
(a) an ESR measurement no greater than 25 mm per hour; or
(b) a CRP measurement no greater than 10 mg per L; or
(c) an ESR or CRP measurement reduced by at least 20% from baseline.
Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.
The authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.
All measurements provided must be no more than 1 month old at the time of application.
A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.
All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.
Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.
Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.
From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.
A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis, AND

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3436W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1481.56	38.30	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3437X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1481.56	38.30	Simponi [JC]

▪ GOLIMUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis, AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND

Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5

years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab for adult patients with severe active psoriatic arthritis.
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.
Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab only.
Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.
Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.
Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.
Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.
Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
Grandfather patients - ustekinumab only.
For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3432P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1481.56	38.30	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3433Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1481.56	38.30	Simponi [JC]

▪ GOLIMUMAB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, AND

Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab or infliximab in this treatment cycle, AND

Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, AND

Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

Authority required

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis, AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, AND

Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, AND

Patient must be eligible to receive further bDMARD therapy.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.
Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.
From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.
A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the

erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

Clinical criteria:

Patient must have active, or a documented history of active, ankylosing spondylitis, AND

Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3434R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1481.56	38.30	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3435T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1481.56	38.30	Simponi [JC]

▪ GOLIMUMAB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe active psoriatic arthritis, AND

Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, AND

Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, AND

Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR

Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis, AND

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, AND

Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or ustekinumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.
Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.
Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
Grandfather patients - ustekinumab only.
For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3430M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1481.56	38.30	Simponi [JC]

golimumab 50 mg/0.5 mL injection, 0.5 mL syringe

3431N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	1481.56	38.30	Simponi [JC]

Interleukin inhibitors

▪ SECUKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, secukinumab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, secukinumab and ustekinumab only.
Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.
Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.
Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.
Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Application for approval for initial treatment.
Applications for a course of initial treatment should be made in the following situations:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
(iii) patients who wish to recommence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab, etanercept and secukinumab, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.
Grandfather patients (secukinumab only).
Applications for patients who commenced treatment with secukinumab for chronic plaque psoriasis prior to 1 September 2015 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not

been treated with a biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Application for continuing treatment.
Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.
For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
(4) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.
(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 3, Whole body (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, AND

Patient must have been receiving treatment with this drug for this condition prior to 1 September 2015, AND

Patient must have had a Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing treatment with this drug, AND

Patient must have demonstrated a response to treatment as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with this drug (whole body), AND

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug) and the most recent PASI assessment; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

The most recent PASI assessment must be no more than 1 month old at the time of application.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

Note A PASI assessment of the patient's response to this initial PBS-subsidised course of therapy must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND

Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the

patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 3, Face, hand, foot (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, AND

Patient must have been receiving treatment with this drug for this condition prior to 1 September 2015, AND

Patient must have had disease, prior to treatment with this drug, classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling were rated as severe or very severe; or (ii) the skin area affected was 30% or more of the face, palm of a hand or sole of a foot, AND

Patient must have demonstrated a response to treatment as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with this drug (face, hand, foot), AND

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug) and the most recent PASI assessment; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The PASI assessment must be performed on the same affected area as assessed at baseline or prior to initiation of treatment with this drug.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

Note A PASI assessment of the patient's response to this initial PBS-subsidised course of therapy must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND

Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 3, Whole body or Face, hand, foot (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) or Continuing treatment, Whole body or Face, hand, foot - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 3, Whole body (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) restriction to complete 24 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 3, Face, hand, foot (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) restriction to complete 24 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, AND

The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

secukinumab 150 mg/mL injection, 2 x 1 mL injection devices

10425Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1763.56	38.30	Cosentyx [NV]

▪ SECUKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, secukinumab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, secukinumab and ustekinumab only.
Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.
Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.
Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.
Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Application for approval for initial treatment.
Applications for a course of initial treatment should be made in the following situations:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iii) patients who wish to recommence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab, etanercept and secukinumab, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.
Grandfather patients (secukinumab only).
Applications for patients who commenced treatment with secukinumab for chronic plaque psoriasis prior to 1 September 2015 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Application for continuing treatment.
Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.
For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
(4) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.
(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, AND

Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, AND

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, AND

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, AND

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, AND

Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, AND

Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, AND

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, AND

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, AND

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, AND

Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment) restriction to complete 16 weeks treatment, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

secukinumab 150 mg/mL injection, 2 x 1 mL injection devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10494H	1	6	..	1763.56	38.30	Cosentyx [NV]

▪ USTEKINUMAB

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis, AND

Patient must have been receiving treatment with this drug for this condition prior to 1 May 2016, AND

Patient must be receiving treatment with this drug for this condition at the time of application, AND

Patient must have demonstrated a response to treatment as specified in the criteria for continuing PBS-subsidised treatment with this drug, AND

Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or ustekinumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis, AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND

Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab for adult patients with severe active psoriatic arthritis.
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.
Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab only.
Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.
Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.
Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.
Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.
Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - ustekinumab only.
For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

10767Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	4379.18	38.30	Stelara [JC]

▪ USTEKINUMAB

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe active psoriatic arthritis, AND

Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, AND

Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, AND

Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR

Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, AND

Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis, AND

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, AND

Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, AND

Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or ustekinumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab for adult patients with severe active psoriatic arthritis.
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.
Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab only.
Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.
Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.
Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.
Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.
Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the

date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
Grandfather patients - ustekinumab only.
For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

10774C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	4379.18	38.30	Stelara [JC]

▪ USTEKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, secukinumab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, secukinumab and ustekinumab only.
Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.
Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from

this condition in respect of applications approved prior to 1 December 2007.
Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.
Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Application for approval for initial treatment.
Applications for a course of initial treatment should be made in the following situations:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
(iii) patients who wish to recommence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab, etanercept and secukinumab, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.
Grandfather patients (secukinumab only).
Applications for patients who commenced treatment with secukinumab for chronic plaque psoriasis prior to 1 September 2015 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Application for continuing treatment.
Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.
For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
(4) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.
(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND

Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND

Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, AND

The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

9305R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	4379.18	38.30	Stelara [JC]

▪ USTEKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, secukinumab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, secukinumab and ustekinumab only.
Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.
Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.
Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.
Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Application for approval for initial treatment.
Applications for a course of initial treatment should be made in the following situations:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
(iii) patients who wish to recommence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab, etanercept and secukinumab, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.
Grandfather patients (secukinumab only).
Applications for patients who commenced treatment with secukinumab for chronic plaque psoriasis prior to 1 September 2015 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Application for continuing treatment.
Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.
For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
(4) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.
(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, AND

Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, AND

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, AND

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, AND

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, AND

Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, AND

Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, AND

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, AND

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, AND

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, AND

Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 28 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment) restriction to complete 28 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 28 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment) restriction to complete 28 weeks treatment, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9304Q	1	2	..	4379.18	38.30	Stelara [JC]

Calcineurin inhibitors

▪ CYCLOSPORIN

Caution Careful monitoring of patients is mandatory.

cyclosporin 10 mg capsule, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	
8657P	2	3	..	*90.43	38.30	Neoral 10 [NV]	

cyclosporin 100 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8660T	2	3	..	*366.39	38.30	[a] Cyclosporin Sandoz [SZ]	[a] Neoral 100 [NV]

cyclosporin 100 mg/mL oral liquid, 50 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	
8661W	2	3	..	*706.97	38.30	Neoral [NV]	

cyclosporin 25 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8658Q	2	3	..	*92.99	38.30	[a] Cyclosporin Sandoz [SZ]	[a] Neoral 25 [NV]

cyclosporin 50 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8659R	2	3	..	*182.21	38.30	[a] Cyclosporin Sandoz [SZ]	[a] Neoral 50 [NV]

▪ TACROLIMUS

Caution Careful monitoring of patients is mandatory.

tacrolimus 1 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8647D	1	3	..	282.48	38.30	[a] Pharmacor Tacrolimus 1 [CR] [a] TACROLIMUS APOTEX [TX]	[a] Prograf [LL] [a] Tacrolimus Sandoz [SZ]

tacrolimus 1 mg capsule: modified release, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5300Y	1	3	..	171.79	38.30	Prograf XL [LL]

tacrolimus 5 mg capsule, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8648E	1	3	..	699.68	38.30	[a] Pharmacor Tacrolimus 5 [CR] [a] TACROLIMUS APOTEX [TX]	[a] Prograf [LL] [a] Tacrolimus Sandoz [SZ]

tacrolimus 5 mg capsule: modified release, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5451X	1	3	..	421.68	38.30	Prograf XL [LL]

tacrolimus 500 microgram capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8646C	1	3	..	144.90	38.30	[a] Pharmacor Tacrolimus 0.5 [CR] [a] TACROLIMUS APOTEX [TX]	[a] Prograf [LL] [a] Tacrolimus Sandoz [SZ]

tacrolimus 500 microgram capsule: modified release, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5299X	1	3	..	50.76	38.30	Prograf XL [LL]

Other immunosuppressants

▪ AZATHIOPRINE

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

azathioprine 25 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2688L NP	1	5	..	25.64	26.81	[a] APO-Azathioprine [TX] [a] Azathioprine Sandoz [SZ]	[a] Azathioprine GH [GQ] [a] Imuran [AS]

azathioprine 50 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2687K NP	1	5	..	36.34	37.51	[a] APO-Azathioprine [TX] [a] Azapin [RW] [a] Azathioprine GH [GQ] [a] GenRx Azathioprine [GX] [a] Imuran [AS]	[a] Azamun [ED] [a] Azathioprine AN [EA] [a] Azathioprine Sandoz [SZ] [a] Imazan [ER] [a] Thioprine 50 [AF]

▪ METHOTREXATE

methotrexate 10 mg tablet, 15

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2272N	1	3	..	22.52	23.69	Methoblastin [PF]

methotrexate 2.5 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1622J	1	5	..	16.25	17.42	Methoblastin [PF]

▪ METHOTREXATE

Restricted benefit

Patients requiring doses greater than 20 mg per week

methotrexate 10 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1623K	1	2	..	50.74	38.30	Methoblastin [PF]

▪ MUSCULO-SKELETAL SYSTEM

▪ ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS

Acetic acid derivatives and related substances

▪ DICLOFENAC

diclofenac sodium 100 mg suppository, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1302M NP MW	2	3	..	*26.85	28.02	Voltaren 100 [NV]

diclofenac sodium 100 mg suppository, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5079H DP	2	..	..	*26.85	28.02	Voltaren 100 [NV]

▪ DICLOFENAC

Restricted benefit

Chronic arthropathies (including osteoarthritis) with an inflammatory component

Restricted benefit

Bone pain due to malignant disease

diclofenac sodium 25 mg tablet: enteric, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1299J NP	2	3	..	*13.79	14.96	[a] APO-Diclofenac [TX] [a] Clonac 25 [RW] [a] Diclofenac-GA [ED] [a] Fenac 25 [AF]	[a] Chem mart Diclofenac [CH] [a] Diclofenac AN [EA] [a] Diclofenac Sandoz [SZ] [a] Terry White Chemists Diclofenac [TW]
			[B]2.44	*16.23	14.96	[a] Voltaren 25 [NV]	

diclofenac sodium 25 mg tablet: enteric, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5076E DP	2	..	..	*13.79	14.96	[a] APO-Diclofenac [TX] [a] Clonac 25 [RW] [a] Diclofenac-GA [ED] [a] Fenac 25 [AF]	[a] Chem mart Diclofenac [CH] [a] Diclofenac AN [EA] [a] Diclofenac Sandoz [SZ] [a] Terry White Chemists Diclofenac [TW]
			[B]2.44	*16.23	14.96	[a] Voltaren 25 [NV]	

diclofenac sodium 50 mg tablet: enteric, 50

1300K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	12.75	13.92	[a] APO-Diclofenac [TX] [a] Clonac 50 [RW] [a] Diclofenac-GA [ED] [a] Fenac [AF]	[a] Chem mart Diclofenac [CH] [a] Diclofenac AN [EA] [a] Diclofenac Sandoz [SZ] [a] Terry White Chemists Diclofenac [TW]
			[B]2.45	15.20	13.92	[a] Voltaren 50 [NV]	

diclofenac sodium 50 mg tablet: enteric, 50

5077F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	12.75	13.92	[a] APO-Diclofenac [TX] [a] Clonac 50 [RW] [a] Diclofenac-GA [ED] [a] Fenac [AF]	[a] Chem mart Diclofenac [CH] [a] Diclofenac AN [EA] [a] Diclofenac Sandoz [SZ] [a] Terry White Chemists Diclofenac [TW]
			[B]2.45	15.20	13.92	[a] Voltaren 50 [NV]	

▪ INDOMETHACIN

indomethacin 100 mg suppository, 20

2757D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	3	..	*24.41	25.58	Indocid [AS]

indomethacin 100 mg suppository, 20

5128X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	2	..	..	*24.41	25.58	Indocid [AS]

▪ INDOMETHACIN

Restricted benefit

Chronic arthropathies (including osteoarthritis) with an inflammatory component

Restricted benefit

Bone pain due to malignant disease

indomethacin 25 mg capsule, 50

2454E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	3	..	*16.03	17.20	[a] Arthrexin [AF]
			[B]4.04	*20.07	17.20	[a] Indocid [AS]

indomethacin 25 mg capsule, 50

5126T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	2	..	..	*16.03	17.20	[a] Arthrexin [AF]
			[B]4.04	*20.07	17.20	[a] Indocid [AS]

Oxicams

▪ MELOXICAM

Note The use of meloxicam for the treatment of the following conditions is not subsidised through the PBS:
(a) acute pain;
(b) soft tissue injury;
(c) arthrosis without an inflammatory component.

Note Pharmaceutical benefits that have the form meloxicam tablet 7.5 mg and pharmaceutical benefits that have the form meloxicam capsule 7.5 mg are equivalent for the purposes of substitution.

Restricted benefit

Symptomatic treatment of osteoarthritis

Restricted benefit

Symptomatic treatment of rheumatoid arthritis

meloxicam 7.5 mg capsule, 30

8887R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	13.89	15.06	[a] APO-Meloxicam [TX] [a] Melox 7.5 [EA] [a] Movalis 7.5 [RW]	[a] Chem mart Meloxicam [CH] [a] Meloxicam Sandoz [SZ] [a] Terry White Chemists Meloxicam [TW]
			[B]2.50	16.39	15.06	[a] Mobic [BY]	

meloxicam 7.5 mg tablet, 30

8561N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	13.89	15.06	[a] APO-Meloxicam [TX]	[a] Chem mart Meloxicam 7.5 mg [CH]
						[a] GenRx Meloxicam [GX]	[a] Meloxiauro 7.5 [DO]
						[a] Meloxibell [GQ]	[a] Meloxicam AN [EA]
						[a] Meloxicam-GA [ED]	[a] Meloxicam Ranbaxy [RA]
						[a] Meloxicam Sandoz [SZ]	[a] Movalis 7.5 [RW]
						[a] Moxicam 7.5 [AF]	[a] Pharmacor Meloxicam 7.5 [CR]
						[a] Terry White Chemists Meloxicam 7.5 mg [TW]	
			[B]2.50	16.39	15.06	[a] Mobic [BY]	

▪ MELOXICAM

Note The use of meloxicam for the treatment of the following conditions is not subsidised through the PBS:
(a) acute pain;
(b) soft tissue injury;
(c) arthrosis without an inflammatory component.

Note Pharmaceutical benefits that have the form meloxicam tablet 15 mg and pharmaceutical benefits that have the form meloxicam capsule 15 mg are equivalent for the purposes of substitution.

Restricted benefit

Symptomatic treatment of osteoarthritis

Restricted benefit

Symptomatic treatment of rheumatoid arthritis

meloxicam 15 mg capsule, 30

8888T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	15.48	16.65	[a] APO-Meloxicam [TX]	[a] Chem mart Meloxicam [CH]
						[a] Melox 15 [EA]	[a] Meloxicam Sandoz [SZ]
						[a] Movalis 15 [RW]	[a] Terry White Chemists Meloxicam [TW]
			[B]2.50	17.98	16.65	[a] Mobic [BY]	

meloxicam 15 mg tablet, 30

8562P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	15.48	16.65	[a] APO-Meloxicam [TX]	[a] Chem mart Meloxicam 15 mg [CH]
						[a] GenRx Meloxicam [GX]	[a] Meloxiauro 15 [DO]
						[a] Meloxibell [GQ]	[a] Meloxicam AN [EA]
						[a] Meloxicam-GA [ED]	[a] Meloxicam Ranbaxy [RA]
						[a] Meloxicam Sandoz [SZ]	[a] Movalis 15 [RW]
						[a] Moxicam 15 [AF]	[a] Pharmacor Meloxicam 15 [CR]
						[a] Terry White Chemists Meloxicam 15 mg [TW]	
			[B]2.50	17.98	16.65	[a] Mobic [BY]	

▪ PIROXICAM

Restricted benefit

Chronic arthropathies (including osteoarthritis) with an inflammatory component

piroxicam 10 mg capsule, 50

1897W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	15.45	16.62	[a] Chem mart Piroxicam [CH]	[a] GenRx Piroxicam [GX]
						[a] Mobilis 10 [AF]	[a] Terry White Chemists Piroxicam [TW]
			[B]6.08	21.53	16.62	[a] Feldene [PF]	

piroxicam 10 mg capsule, 50

5203W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	15.45	16.62	[a] Chem mart Piroxicam [CH]	[a] GenRx Piroxicam [GX]
						[a] Mobilis 10 [AF]	[a] Terry White Chemists Piroxicam [TW]
			[B]6.08	21.53	16.62	[a] Feldene [PF]	

piroxicam 10 mg tablet: dispersible, 50

1895R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	3	..	15.45	16.62	Mobilis D-10 [AF]

piroxicam 10 mg tablet: dispersible, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5201R DP	1	..	..	15.45	16.62	Mobilis D-10 [AF]

piroxicam 20 mg capsule, 25

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1898X NP	1	3	..	15.20	16.37	[a] Chem mart Piroxicam [CH] [a] Mobilis 20 [AF]	[a] GenRx Piroxicam [GX] [a] Terry White Chemists Piroxicam [TW]
			[B]5.86	21.06	16.37	[a] Feldene [PF]	

piroxicam 20 mg capsule, 25

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5204X DP	1	..	..	15.20	16.37	[a] Chem mart Piroxicam [CH] [a] Mobilis 20 [AF]	[a] GenRx Piroxicam [GX] [a] Terry White Chemists Piroxicam [TW]
			[B]5.86	21.06	16.37	[a] Feldene [PF]	

piroxicam 20 mg tablet: dispersible, 25

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1896T NP	1	3	..	15.20	16.37	[a] Mobilis D-20 [AF]
			[B]6.86	22.06	16.37	[a] Feldene-D [PF]

piroxicam 20 mg tablet: dispersible, 25

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5202T DP	1	..	..	15.20	16.37	[a] Mobilis D-20 [AF]
			[B]6.86	22.06	16.37	[a] Feldene-D [PF]

Propionic acid derivatives

▪ IBUPROFEN

ibuprofen 400 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3192B NP MW	1	..	..	12.71	13.88	Brufen [GO]

ibuprofen 400 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5124Q DP	1	..	..	12.71	13.88	Brufen [GO]

▪ IBUPROFEN

Restricted benefit

Chronic arthropathies (including osteoarthritis) with an inflammatory component

Restricted benefit

Bone pain due to malignant disease

ibuprofen 400 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3190X NP	3	3	..	*17.28	18.45	Brufen [GO]

ibuprofen 400 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5123P DP	3	..	..	*17.28	18.45	Brufen [GO]

▪ KETOPROFEN

Restricted benefit

Chronic arthropathies (including osteoarthritis) with an inflammatory component

ketoprofen 200 mg capsule: modified release, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1590Q NP	1	3	..	21.45	22.62	[a] Oruvail SR [AV]
			[B]1.92	23.37	22.62	[a] Orudis SR 200 [SW]

ketoprofen 200 mg capsule: modified release, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5136H DP	1	..	..	21.45	22.62	[a] Oruvail SR [AV]
			[B]1.92	23.37	22.62	[a] Orudis SR 200 [SW]

▪ NAPROXEN

Restricted benefit

Chronic arthropathies (including osteoarthritis) with an inflammatory component

Restricted benefit

Bone pain due to malignant disease

naproxen 1 g tablet: modified release, 28

1615B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	3	..	16.98	18.15	[a] Proxen SR 1000 [IY]
			[B]1.12	18.10	18.15	[a] Naprosyn SR1000 [IX]

naproxen 1 g tablet: modified release, 28

5179N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	16.98	18.15	[a] Proxen SR 1000 [IY]
			[B]1.12	18.10	18.15	[a] Naprosyn SR1000 [IX]

naproxen 250 mg tablet, 50

1674D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	3	..	*17.69	18.86	[a] Inza 250 [AF]
			[B]2.24	*19.93	18.86	[a] Naprosyn [IX]

naproxen 250 mg tablet, 50

5176K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	2	..	..	*17.69	18.86	[a] Inza 250 [AF]
			[B]2.24	*19.93	18.86	[a] Naprosyn [IX]

naproxen 500 mg tablet, 50

1659H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	3	..	15.79	16.96	[a] Inza 500 [AF]
			[B]1.12	16.91	16.96	[a] Naprosyn [IX]

naproxen 500 mg tablet, 50

5177L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	15.79	16.96	[a] Inza 500 [AF]
			[B]1.12	16.91	16.96	[a] Naprosyn [IX]

naproxen 750 mg tablet: modified release, 28

1614Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	3	..	15.34	16.51	[a] Proxen SR 750 [IY]
			[B]1.06	16.40	16.51	[a] Naprosyn SR750 [IX]

naproxen 750 mg tablet: modified release, 28

5178M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	15.34	16.51	[a] Proxen SR 750 [IY]
			[B]1.06	16.40	16.51	[a] Naprosyn SR750 [IX]

▪ NAPROXEN

Authority required (STREAMLINED)

4159

Chronic arthropathies (including osteoarthritis)

Clinical criteria:

The condition must have an inflammatory component, AND

Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

Authority required (STREAMLINED)

4124

Bone pain

Clinical criteria:

The condition must be due to malignant disease, AND

Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

naproxen 125 mg/5 mL oral liquid, 474 mL

1658G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	3	..	120.60	38.30	Phebra Naproxen Suspension [PL]

▪ NAPROXEN

Note Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

Restricted benefit

Chronic arthropathies (including osteoarthritis) with an inflammatory component

Restricted benefit

Bone pain due to malignant disease

naproxen sodium 550 mg tablet, 50

1795L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	3	..	15.94	17.11	[a] Crysanal [IY]
			[B]1.89	17.83	17.11	[a] Anaprox 550 [IX]

naproxen sodium 550 mg tablet, 50

5186Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	15.94	17.11	[a] Crysanal [IY]
			[B]1.89	17.83	17.11	[a] Anaprox 550 [IX]

Fenamates

▪ MEFENAMIC ACID

Restricted benefit

Dysmenorrhoea

Restricted benefit

Menorrhagia

mefenamic acid 250 mg capsule, 50

1824B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	20.13	21.30	Ponstan [PF]

Coxibs

▪ CELECOXIB

Note The use of this drug for the treatment of the following conditions is not subsidised through the PBS:
(a) acute pain;
(b) soft tissue injury;
(c) arthrosis without an inflammatory component.

Restricted benefit

Osteoarthritis

Clinical criteria:

The treatment must be for symptomatic treatment.

Restricted benefit

Rheumatoid arthritis

Clinical criteria:

The treatment must be for symptomatic treatment.

celecoxib 100 mg capsule, 60

8439E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	22.03	23.20	[a] APO-Celecoxib [TX]	[a] Blooms the Chemist Celecoxib [IB]
						[a] Celaxib [AF]	[a] Celebrex [PF]
						[a] Celecoxib Actavis [ED]	[a] Celecoxib AN [EA]
						[a] Celecoxib GH [GQ]	[a] Celecoxib RBX [RA]
						[a] Celecoxib Sandoz [SZ]	[a] Celexi [RW]
						[a] Chem mart Celecoxib [CH]	[a] Kudeq [FZ]
						[a] Terry White Chemists Celecoxib [TW]	

celecoxib 200 mg capsule, 30

8440F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	22.03	23.20	[a] APO-Celecoxib [TX]	[a] Blooms the Chemist Celecoxib [IB]
						[a] Celaxib [AF]	[a] Celebrex [PF]
						[a] Celecoxib Actavis [ED]	[a] Celecoxib AN [EA]
						[a] Celecoxib GH [GQ]	[a] Celecoxib RBX [RA]
						[a] Celecoxib Sandoz [SZ]	[a] Celexi [RW]
						[a] Chem mart Celecoxib [CH]	[a] Kudeq [FZ]
						[a] Terry White Chemists Celecoxib [TW]	

SPECIFIC ANTIRHEUMATIC AGENTS

Quinolines

▪ HYDROXYCHLOROQUINE

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

hydroxychloroquine sulfate 200 mg tablet, 100

1512N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	30.84	32.01	[a] APO- Hydroxychloroquine [TX]	[a] Chem mart Hydroxychloroquine [CH]
						[a] Hequinel [RW]	[a] Hydroxychloroquine Actavis [ED]
						[a] Hydroxychloroquine AN [EA]	[a] Hydroxychloroquine GH [GQ]
						[a] Hydroxychloroquine RBX [RA]	[a] Plaquenil [SW]
						[a] Terry White Chemists Hydroxychloroquine [TW]	

Gold preparations

▪ AURANOFIN

Caution Regular blood and urine checks are essential.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

auranofin 3 mg tablet, 60

1095P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	59.76	38.30	Ridaura [GH]

▪ AUROTHIOMALATE SODIUM

Caution Regular blood and urine checks are essential.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

aurothiomalate sodium 10 mg/0.5 mL injection, 10 x 0.5 mL ampoules

2016D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	76.81	38.30	Myocrisin [SW]

aurothiomalate sodium 20 mg/0.5 mL injection, 10 x 0.5 mL ampoules

2017E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	1	..	112.56	38.30	Myocrisin [SW]

aurothiomalate sodium 50 mg/0.5 mL injection, 10 x 0.5 mL ampoules

2018F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	1	..	136.55	38.30	Myocrisin [SW]

Penicillamine and similar agents

▪ PENICILLAMINE

Caution Regular blood and urine checks are essential.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

penicillamine 125 mg tablet, 100

2721F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	1	..	31.25	32.42	D-Penamine [AL]

penicillamine 250 mg tablet, 100

2838J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	1	..	50.68	38.30	D-Penamine [AL]

MUSCLE RELAXANTS

MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

Other centrally acting agents

BACLOFEN

baclofen 10 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2729P NP	1	5	..	21.58	22.75	[a] Chem mart Baclofen [CH] [a] GenRx Baclofen [GX] [a] Stelax 10 [RW]	[a] Clofen 10 [AF] [a] Lioresal 10 [NV] [a] Terry White Chemists Baclofen [TW]

baclofen 25 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2730Q NP	1	5	..	34.81	35.98	[a] Chem mart Baclofen [CH] [a] GenRx Baclofen [GX] [a] Stelax 25 [RW]	[a] Clofen 25 [AF] [a] Lioresal 25 [NV] [a] Terry White Chemists Baclofen [TW]

MUSCLE RELAXANTS, DIRECTLY ACTING AGENTS

Dantrolene and derivatives

DANTROLENE

Restricted benefit

Treatment of chronic spasticity

dantrolene sodium 25 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1779P NP	1	2	..	75.00	38.30	Dantrium [PF]

dantrolene sodium 50 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1780Q NP	1	2	..	75.53	38.30	Dantrium [PF]

ANTIGOUT PREPARATIONS

ANTIGOUT PREPARATIONS

Preparations inhibiting uric acid production

ALLOPURINOL

Note The dose should be adjusted in accordance with renal function.

allopurinol 300 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2604C NP	1	2	..	12.74	13.91	[a] Allopurinol Sandoz [SZ] [a] APO-Allopurinol [TX] [a] GenRx Allopurinol [GX] [a] Terry White Chemists Allopurinol [TW]	[a] Allosig [RF] [a] Chem mart Allopurinol [CH] [a] Progout 300 [AF]
			[B]3.48	16.22	13.91	[a] Zyloprim [RW]	

ALLOPURINOL

Note The dose should be adjusted in accordance with renal function.

Note For item codes 2600W and 1557Y, pharmaceutical benefits that have the form tablet 100 mg are equivalent for the purposes of substitution.

allopurinol 100 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1557Y NP	2	2	..	*14.39	15.56	[a] Progout 100 [AF]

allopurinol 100 mg tablet, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2600W NP	1	2	..	14.38	15.55	[a] Allopurinol Sandoz [SZ] [a] APO-Allopurinol [TX] [a] GenRx Allopurinol [GX]	[a] Allosig [RF] [a] Chem mart Allopurinol [CH] [a] Terry White Chemists Allopurinol [TW]

[B]3.47	17.85	15.55	[a]	Zyloprim [RW]

▪ FEBUXOSTAT

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required
Chronic gout
Clinical criteria:
The condition must be either chronic gouty arthritis or chronic tophaceous gout, AND
Patient must have a medical contraindication to allopurinol; OR
Patient must have a documented history of allopurinol hypersensitivity syndrome; OR
Patient must have an intolerance to allopurinol necessitating permanent treatment discontinuation.

febuxostat 80mg tablet, 28

10445R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	50.27	38.30	Adenuric [FK]

Preparations increasing uric acid excretion

▪ PROBENECID

probenecid 500 mg tablet, 100

1940D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	70.24	38.30	Pro-Cid [PL]

Preparations with no effect on uric acid metabolism

▪ COLCHICINE

colchicine 500 microgram tablet, 30

3410L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $		Brand Name and Manufacturer
NP	1	5	..	14.40	15.57	[a]	Lengout [LN]
			[B]2.90	17.30	15.57	[a]	Colgout [AS]

▪ DRUGS FOR TREATMENT OF BONE DISEASES

DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

Bisphosphonates

▪ ALENDRONATE

Restricted benefit
Corticosteroid-induced osteoporosis
Clinical criteria:
Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, AND
Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, AND
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.
The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Note Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

Restricted benefit
Osteoporosis
Clinical criteria:
Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, AND
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.
Population criteria:
Patient must be aged 70 years or older.
The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Note Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

Restricted benefit
Established osteoporosis
Clinical criteria:
Patient must have fracture due to minimal trauma, AND
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

alendronate 70 mg tablet, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8511Y NP	1	5	..	15.32	16.49	[a] Alendrobell 70mg [GQ] [a] Alendronate-GA [ED] [a] Alendro Once Weekly [RW] [a] Densate 70 [DO]	[a] Alendronate AN [EA] [a] Alendronate Sandoz [SZ] [a] APO-Alendronate [TX] [a] Fonat [AL]

▪ CLODRONATE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Hypercalcaemia of malignancy
Clinical criteria:
Patient must have a malignancy refractory to anti-neoplastic therapy.

Restricted benefit
Multiple myeloma

Restricted benefit
Bone metastases
Clinical criteria:
The condition must be due to breast cancer.

clodronate sodium 400 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8132B NP	1	2	..	308.59	38.30	Bonefos [BN]

clodronate sodium 800 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8265B NP	1	2	..	364.99	38.30	Bonefos 800 mg [BN]

▪ IBANDRONATE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Bone metastases
Clinical criteria:
The condition must be due to breast cancer.

ibandronate 50 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9357L NP	1	2	..	316.71	38.30	Bondronat [RO]

▪ PAMIDRONATE DISODIUM

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Symptomatic Paget disease of bone

pamidronate disodium 15 mg/5 mL injection, 5 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8461H NP	4	..	..	*69.81	38.30	Pamisol [HH]

pamidronate disodium 30 mg/10 mL injection, 10 mL vial

8462J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*69.85	38.30	Pamisol [HH]

pamidronate disodium 60 mg/10 mL injection, 10 mL vial

8463K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	69.84	38.30	Pamisol [HH]

▪ RISEDRONATE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Symptomatic Paget disease of bone

risedronate sodium 30 mg tablet, 28

8482K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	1	..	197.16	38.30	Actonel [UA]

▪ RISEDRONATE

Restricted benefit

Corticosteroid-induced osteoporosis

Clinical criteria:

Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, AND

Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Note Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

Restricted benefit

Osteoporosis

Clinical criteria:

Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:

Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Note Anti-resorptive agents in osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

Restricted benefit

Established osteoporosis

Clinical criteria:

Patient must have fracture due to minimal trauma, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

RISEDRONATE SODIUM Tablet 35 mg (enteric coated), 4

8972F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	37.73	38.30	Actonel EC [UA]

risedronate sodium 150 mg tablet, 1

9391G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	40.02	38.30	[a] Acris Once-a-Month [AF] [a] APO-Risedronate [TX]	[a] Actonel Once-a-Month [UA] [a] ATELVIA ONCE-A-MONTH [GN]

						[a] Chem mart Risedronate [CH]	[a] Terry White Chemists Risedronate [TW]

risedronate sodium 35 mg tablet, 4

8621R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	37.73	38.30	[a] Acris Once-a-Week [AF] [a] Risedronate AN [EA] [a] Risedronate Sandoz [SZ]	[a] APO-Risedronate [TX] [a] Risedronate-GA [GN] [a] Risedro once a week [RW]

risedronate sodium 5 mg tablet, 28

8481J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	37.73	38.30	Actonel [UA]

▪ ZOLEDRONIC ACID

Note Pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL vial and pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL bag are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

5710

Symptomatic Paget disease of bone

Only 1 treatment each year per patient will be PBS-subsidised

zoledronic acid 5 mg/100 mL injection, 100 mL bag

10571J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	491.28	38.30	[a] Ostira [HH]

zoledronic acid 5 mg/100 mL injection, 100 mL vial

9350D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	491.28	38.30	[a] Aclasta [NV] [a] Zoledasta [TX]	[a] Osteovan [SZ]

▪ ZOLEDRONIC ACID

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

Note Pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL vial and pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL bag are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

5656

Corticosteroid-induced osteoporosis

Clinical criteria:

Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, AND

Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, AND

Patient must not receive more than one PBS-subsidised treatment per year.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

5765

Osteoporosis

Clinical criteria:

Patient must have a Bone Mineral Density (BMD) T-score of -3.0 or less, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, AND

Patient must not receive more than one PBS-subsidised treatment per year.

Population criteria:

Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

5796

Established osteoporosis

Clinical criteria:

Patient must have fracture due to minimal trauma, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, AND

Patient must not receive more than one PBS-subsidised treatment per year.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

zoledronic acid 5 mg/100 mL injection, 100 mL bag

10555M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	491.28	38.30	[a] Ostira [HH]

zoledronic acid 5 mg/100 mL injection, 100 mL vial

9288W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	491.28	38.30	[a] Aclasta [NV] [a] Zoledasta [TX]	[a] Osteovan [SZ]

Bisphosphonates, combinations

▪ ALENDRONATE + COLECALCIFEROL

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

Authority required (STREAMLINED)

4122

Corticosteroid-induced osteoporosis

Clinical criteria:

Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, AND

Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

4133

Osteoporosis

Clinical criteria:

Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:

Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

4123

Established osteoporosis

Clinical criteria:

Patient must have fracture due to minimal trauma, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

alendronate 70 mg + colecalciferol 140 microgram tablet, 4

9183H

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	39.35	38.30	[a] Alendrobell plus D3 [GQ] [a] Alendronate plus D3-DRLA [RZ] [a] APO-Alendronate Plus D3 70 mg/140 mcg [TX] [a] Dronalen Plus [AL] [a] Terry White Chemists Alendronate Plus D3 70 mg/140 mcg [TW]	[a] Alendronate D3 70 mg/140 microgram [EA] [a] Alendronate Plus D3 Sandoz [SZ] [a] Chem mart Alendronate Plus D3 70 mg/140 mcg [CH] [a] FonatPlus [AF]
		[B]2.49	41.84	38.30	[a] Fosamax Plus 70 mg/140 mcg [MK]	

▪ ALENDRONATE + COLECALCIFEROL

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

Note Fosamax Plus provides a supplemental intake of vitamin D. The amount of colecalciferol present in Fosamax Plus is not sufficient to use as the sole treatment for correction of vitamin D deficiency.

Authority required (STREAMLINED)

4070

Corticosteroid-induced osteoporosis

Clinical criteria:

Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, AND

Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

4110

Osteoporosis

Clinical criteria:

Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:

Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

4087

Established osteoporosis

Clinical criteria:

Patient must have fracture due to minimal trauma, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

alendronate 70 mg + colecalciferol 70 microgram tablet, 4

9012H

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	39.35	38.30	[a] Alendrobell plus D3 [GQ]	[a] Alendronate D3 70 mg/70 microgram [EA]
					[a] Alendronate plus D3-DRLA [RZ]	[a] Alendronate Plus D3 Sandoz [SZ]
					[a] APO-Alendronate Plus D3 70 mg/70 mcg [TX]	[a] Chem mart Alendronate Plus D3 70 mg/70 mcg [CH]
					[a] FonatPlus [AF]	[a] Terry White Chemists Alendronate Plus D3 70 mg/70 mcg [TW]
		[B]2.50	41.85	38.30	[a] Fosamax Plus [MK]	

▪ ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

Authority required (STREAMLINED)

4122

Corticosteroid-induced osteoporosis

Clinical criteria:

Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, AND

Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

4133

Osteoporosis

Clinical criteria:

Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:

Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

4123

Established osteoporosis

Clinical criteria:

Patient must have fracture due to minimal trauma, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack

9351E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	5	..	39.99	38.30	[a] Alendronate Plus D3 and Calcium Sandoz [SZ]	[a] Alendronate Plus D3 Calcium Actavis [EA]
					[a] Dronalen Plus D-Cal [AF]	[a] ReddyMax Plus D-Cal [RZ]
		[B]2.50	42.49	38.30	[a] Fosamax Plus D-Cal [MK]	

▪ RISEDRONATE (&) CALCIUM CARBONATE

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

Authority required (STREAMLINED)

4122

Corticosteroid-induced osteoporosis

Clinical criteria:

Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, AND

Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

4133

Osteoporosis

Clinical criteria:

Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:

Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

4123

Established osteoporosis

Clinical criteria:

Patient must have fracture due to minimal trauma, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

RISEDRONATE SODIUM and CALCIUM CARBONATE Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1

8973G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	44.89	38.30	Actonel EC Combi [UA]

risedronate sodium 35 mg tablet [4] (&) calcium (as carbonate) 500 mg tablet [24], 28

8899J NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	44.89	38.30	Acris Combi [AF]

▪ RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

Authority required (STREAMLINED)

4122

Corticosteroid-induced osteoporosis

Clinical criteria:

Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, AND

Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

4133

Osteoporosis

Clinical criteria:

Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:

Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

4123

Established osteoporosis

Clinical criteria:

Patient must have fracture due to minimal trauma, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8974H NP	‡1	5	..	44.89	38.30	Actonel EC Combi D [UA]

Other drugs affecting bone structure and mineralization

▪ CALCITRIOL

Authority required (STREAMLINED)

5401

Hypocalcaemia

Clinical criteria:

The condition must be due to renal disease.

Authority required (STREAMLINED)

5255

Hypoparathyroidism

Authority required (STREAMLINED)

5089

Hypophosphataemic rickets

Authority required (STREAMLINED)

5114

Vitamin D-resistant rickets

Authority required (STREAMLINED)

5402

Established osteoporosis

Clinical criteria:

Patient must have fracture due to minimal trauma.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

calcitriol 0.25 microgram capsule, 100

2502Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	28.83	30.00	[a] APO-Calcitriol [TX] [a] Calcitriol AN [EA] [a] Calcitriol Sandoz [SZ] [a] Kosteo [RW] [a] Sical [AF]	[a] Calciprox [ER] [a] Calcitriol-GA [ED] [a] GenRx Calcitriol [GX] [a] Rocaltrol [RO]

▪ DENOSUMAB

Note Denosumab is not PBS-subsidised for use in patients who have undergone curative surgical resection.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4504

Giant cell tumour of bone

Clinical criteria:

Patient must be one in whom surgical resection is not feasible; OR

Patient must be one in whom surgical resection is possible but surgery would result in significant morbidity.

Population criteria:

Patient must be an adult; OR

Patient must be a skeletally mature adolescent.

denosumab 120 mg/1.7 mL injection, 1.7 mL vial

10061M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	501.00	38.30	Xgeva [AN]

▪ DENOSUMAB

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4158

Bone metastases

Clinical criteria:

The condition must be due to breast cancer.

Authority required (STREAMLINED)

4150

Bone metastases

Clinical criteria:

The condition must be due to castration-resistant prostate cancer.

denosumab 120 mg/1.7 mL injection, 1.7 mL vial

5110Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	501.00	38.30	Xgeva [AN]

▪ DENOSUMAB

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4314

Osteoporosis

Clinical criteria:

Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less, AND

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

Population criteria:

Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

4347

Established osteoporosis
Clinical criteria:
Patient must have fracture due to minimal trauma, AND
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.
The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.
A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

denosumab 60 mg/mL injection, 1 mL syringe

5457F (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	270.82	38.30	Prolia [AN]

▪ RALOXIFENE

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

Authority required (STREAMLINED)
4071
Established post-menopausal osteoporosis
Clinical criteria:
Patient must have fracture due to minimal trauma, AND
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.
The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.
A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

raloxifene hydrochloride 60 mg tablet, 28

8363E (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	44.18	38.30	[a] APO-Raloxifene [TX] [a] Evifyne [EL] [a] Fixta 60 [DO] [a] Terry White Chemists Raloxifene [TW]	[a] Chem mart Raloxifene [CH] [a] Evista [LY] [a] Raloxifene AN [EA]

▪ STRONTIUM

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

Authority required
Severe established osteoporosis
Clinical criteria:
Patient must have fracture due to minimal trauma, AND
Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, AND
Patient must be at high risk of fracture, AND
Patient must be unable to use other medications for the treatment of osteoporosis due to contraindications or intolerance.
The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.
A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

strontium ranelate 2 g granules, 28 sachets

3036T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	49.13	38.30	Protos 2 g [SE]

▪ TERIPARATIDE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Severe established osteoporosis
Treatment Phase: Initial treatment
Clinical criteria:
Patient must be at very high risk of fracture, AND
Patient must have a bone mineral density (BMD) T-score of -3.0 or less, AND
Patient must have had 2 or more fractures due to minimal trauma, AND

Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses, AND

The treatment must be the sole PBS-subsidised agent, AND

The treatment must not exceed a lifetime maximum of 18 months therapy.

Treatment criteria:

Must be treated by a specialist; OR

Must be treated by a consultant physician.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with teriparatide is initiated.

Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months, strontium ranelate 2 g per day and zoledronic acid 5 mg per annum.

Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.

Note Details of accepted toxicities including severity can be found on the Department of Human Services website at www.humanservices.gov.au.

Authority required

Severe established osteoporosis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug, AND

The treatment must not exceed a lifetime maximum of 18 months therapy.

Note Up to a maximum of 18 pens will be reimbursed through the PBS.

teriparatide 20 microgram injection, 2.4 mL cartridge

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9411H	1	5	..	411.13	38.30	Forteo [LY]

NERVOUS SYSTEM

ANALGESICS

OPIOIDS

Natural opium alkaloids

CODEINE

codeine phosphate 30 mg tablet, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1214X NP	1	..	..	19.73	20.90	Fawns and McAllan Proprietary Limited [FM]

CODEINE

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

codeine phosphate 30 mg tablet, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5063L DP	1	..	..	19.73	20.90	Fawns and McAllan Proprietary Limited [FM]

HYDROMORPHONE

Caution The risk of drug dependence is high.

hydromorphone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8421F NP	1	..	..	29.72	30.89	Dilaudid-HP [MF]

hydromorphone hydrochloride 2 mg/mL injection, 5 x 1 mL ampoules

8420E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	24.66	25.83	Dilaudid [MF]

hydromorphone hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules

8422G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	49.79	38.30	Dilaudid-HP [MF]

hydromorphone hydrochloride 500 mg/50 mL injection, 50 mL vial

8423H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	70.57	38.30	Dilaudid-HP [MF]

▪ HYDROMORPHONE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted benefit

Severe disabling pain

Clinical criteria:

The condition must be unresponsive to non-opioid analgesics.

hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL

5132D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	60.46	38.30	Dilaudid [MF]

hydromorphone hydrochloride 2 mg tablet, 20

5115F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	19.92	21.09	Dilaudid [MF]

hydromorphone hydrochloride 4 mg tablet, 20

5116G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	22.19	23.36	Dilaudid [MF]

hydromorphone hydrochloride 8 mg tablet, 20

5117H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	30.60	31.77	Dilaudid [MF]

▪ HYDROMORPHONE

Caution The risk of drug dependence is high.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Restricted benefit

Severe disabling pain

Clinical criteria:

The condition must be unresponsive to non-opioid analgesics.

hydromorphone hydrochloride 1 mg/mL oral liquid, 473 mL

8424J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	60.46	38.30	Dilaudid [MF]

hydromorphone hydrochloride 2 mg tablet, 20

8541M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	19.92	21.09	Dilaudid [MF]

hydromorphone hydrochloride 4 mg tablet, 20

8542N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	22.19	23.36	Dilaudid [MF]

hydromorphone hydrochloride 8 mg tablet, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8543P NP	1	..	..	30.60	31.77	Dilaudid [MF]

▪ HYDROMORPHONE

Caution The risk of drug dependence is high.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Restricted benefit

Chronic severe disabling pain

Clinical criteria:

The condition must be unresponsive to non-opioid analgesics.

hydromorphone hydrochloride 16 mg tablet: modified release, 14

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9407D NP	1	..	..	50.56	38.30	Jurnista [JC]

hydromorphone hydrochloride 32 mg tablet: modified release, 14

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9408E NP	1	..	..	82.06	38.30	Jurnista [JC]

hydromorphone hydrochloride 4 mg tablet: modified release, 14

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9299K NP	1	..	..	31.35	32.52	Jurnista [JC]

hydromorphone hydrochloride 64 mg tablet: modified release, 14

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9409F NP	1	..	..	134.45	38.30	Jurnista [JC]

hydromorphone hydrochloride 8 mg tablet: modified release, 14

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9406C NP	1	..	..	35.87	37.04	Jurnista [JC]

▪ MORPHINE

Caution The risk of drug dependence is high.

morphine sulfate 10 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1644M NP MW	1	..	..	20.86	22.03	Hospira Pty Limited [HH]

morphine sulfate 15 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1645N NP MW	1	..	..	22.52	23.69	Hospira Pty Limited [HH]

morphine sulfate 30 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1647Q NP	1	..	..	25.02	26.19	Hospira Pty Limited [HH]

morphine tartrate 120 mg/1.5 mL injection, 5 x 1.5 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1607N NP	1	..	..	47.42	38.30	Hospira Pty Limited [HH]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

morphine sulfate 10 mg/mL injection, 5 x 1 mL ampoules

5168B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	20.86	22.03	Hospira Pty Limited [HH]

morphine sulfate 15 mg/mL injection, 5 x 1 mL ampoules

5169C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	22.52	23.69	Hospira Pty Limited [HH]

morphine sulfate 30 mg/mL injection, 5 x 1 mL ampoules

5170D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	25.02	26.19	Hospira Pty Limited [HH]

▪ MORPHINE

Caution The risk of drug dependence is high.

Authority required

Chronic severe disabling pain

Clinical criteria:

The condition must be due to cancer, AND

The condition must be unresponsive to non-opioid analgesics.

morphine sulfate 200 mg granules: modified release, 28 sachets

8454Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	153.89	38.30	MS Contin Suspension 200 mg [MF]

morphine sulfate 200 mg tablet: modified release, 28

8453X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	115.81	38.30	MS Contin [MF]

▪ MORPHINE

Caution The risk of drug dependence is high.

Restricted benefit

Severe disabling pain

Clinical criteria:

The condition must be due to cancer, AND

The condition must be unresponsive to non-opioid analgesics.

morphine sulfate 10 mg tablet, 20

8669G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	17.84	19.01	Sevredol [MF]

morphine sulfate 20 mg tablet, 20

8670H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	18.66	19.83	Sevredol [MF]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Restricted benefit

Severe disabling pain

Clinical criteria:

The condition must be unresponsive to non-opioid analgesics.

morphine hydrochloride 10 mg/mL oral liquid, 200 mL

2124T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	28.75	29.92	Ordine 10 [MF]

morphine hydrochloride 2 mg/mL oral liquid, 200 mL

2122Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	23.07	24.24	Ordine 2 [MF]

morphine hydrochloride 5 mg/mL oral liquid, 200 mL

2123R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	25.16	26.33	Ordine 5 [MF]

morphine sulfate 30 mg tablet, 20

1646P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	17.59	18.76	Anamorph [RW]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Restricted benefit

Chronic severe disabling pain

Clinical criteria:

The condition must be unresponsive to non-opioid analgesics.

morphine Capsule 10 mg (containing sustained release pellets), 28

8349K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	22.81	23.98	Kapanol [YN]

morphine Capsule 100 mg (containing sustained release pellets), 28

2841M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	69.09	38.30	Kapanol [YN]

morphine Capsule 20 mg (containing sustained release pellets), 28

2839K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	27.14	28.31	Kapanol [YN]

morphine Capsule 50 mg (containing sustained release pellets), 28

2840L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	43.05	38.30	Kapanol [YN]

morphine Sachet containing controlled release granules for oral suspension, 30 mg per sachet, 28

8146R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	61.46	38.30	MS Contin Suspension 30 mg [MF]

morphine Sachet containing controlled release granules for oral suspension, 60 mg per sachet, 28

8305D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	68.55	38.30	MS Contin Suspension 60 mg [MF]

morphine sulfate 10 mg tablet: modified release, 28

1653B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	22.82	23.99	[a] Momex SR 10 [RW] [a] MORPHINE MR APOTEX [TX]	[a] Morphine MR AN [EA] [a] MS Contin [MF]

morphine sulfate 100 mg granules: modified release, 28 sachets

8306E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	83.55	38.30	MS Contin Suspension 100 mg [MF]

morphine sulfate 100 mg tablet: modified release, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1656E NP	1	..	..	70.95	38.30	[a] Momex SR 100 [RW] [a] MORPHINE MR APOTEX [TX]	[a] Morphine MR AN [EA] [a] MS Contin [MF]

morphine sulfate 120 mg capsule: modified release, 14

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8494C NP	1	..	..	54.17	38.30	MS Mono [MF]

morphine sulfate 15 mg tablet: modified release, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8489T NP	1	..	..	26.46	27.63	MS Contin [MF]

morphine sulfate 20 mg granules: modified release, 28 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8490W NP	1	..	..	59.84	38.30	MS Contin Suspension 20 mg [MF]

morphine sulfate 30 mg capsule: modified release, 14

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8491X NP	1	..	..	26.45	27.62	MS Mono [MF]

morphine sulfate 30 mg tablet: modified release, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1654C NP	1	..	..	36.60	37.77	[a] Momex SR 30 [RW] [a] MORPHINE MR APOTEX [TX]	[a] Morphine MR AN [EA] [a] MS Contin [MF]

morphine sulfate 5 mg tablet: modified release, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8035X NP	1	..	..	20.70	21.87	MS Contin [MF]

morphine sulfate 60 mg capsule: modified release, 14

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8492Y NP	1	..	..	36.58	37.75	MS Mono [MF]

morphine sulfate 60 mg tablet: modified release, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1655D NP	1	..	..	54.18	38.30	[a] Momex SR 60 [RW] [a] MORPHINE MR APOTEX [TX]	[a] Morphine MR AN [EA] [a] MS Contin [MF]

morphine sulfate 90 mg capsule: modified release, 14

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8493B NP	1	..	..	41.41	38.30	MS Mono [MF]

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted benefit

Severe disabling pain

Clinical criteria:

The condition must be unresponsive to non-opioid analgesics.

morphine hydrochloride 10 mg/mL oral liquid, 200 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5239R DP	1	..	..	28.75	29.92	Ordine 10 [MF]

morphine hydrochloride 2 mg/mL oral liquid, 200 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5237P DP	1	..	..	23.07	24.24	Ordine 2 [MF]

morphine hydrochloride 5 mg/mL oral liquid, 200 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5238Q DP	1	..	..	25.16	26.33	Ordine 5 [MF]

morphine sulfate 30 mg tablet, 20

5163R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	17.59	18.76	Anamorph [RW]

▪ OXYCODONE

Caution The risk of drug dependence is high.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Restricted benefit

Severe disabling pain

Clinical criteria:

The condition must be unresponsive to non-opioid analgesics.

oxycodone 30 mg suppository, 12

2481N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	43.36	38.30	Proladone [PL]

oxycodone hydrochloride 10 mg capsule, 20

8501K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	17.93	19.10	OxyNorm [MF]

oxycodone hydrochloride 20 mg capsule, 20

8502L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	21.37	22.54	OxyNorm [MF]

oxycodone hydrochloride 5 mg capsule, 20

8464L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	15.65	16.82	OxyNorm [MF]

oxycodone hydrochloride 5 mg tablet, 20

2622B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	15.65	16.82	[a] Endone [QA]	[a] Mayne Pharma Oxycodone IR [YN]
						[a] Oxycodone Aspen [FM]	

oxycodone hydrochloride 5 mg/5 mL oral liquid, 250 mL

8644Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	23.42	24.59	OxyNorm Liquid 5mg/5mL [MF]

▪ OXYCODONE

Caution The risk of drug dependence is high.

Note Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.

Restricted benefit

Severe disabling pain

Clinical criteria:

The condition must be unresponsive to non-opioid analgesics.

oxycodone 30 mg suppository, 12

5194J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	43.36	38.30	Proladone [PL]

oxycodone hydrochloride 10 mg capsule, 20

5197M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	17.93	19.10	OxyNorm [MF]

oxycodone hydrochloride 5 mg capsule, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5191F DP	1	..	..	15.65	16.82	OxyNorm [MF]

oxycodone hydrochloride 5 mg tablet, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5195K DP	1	..	..	15.65	16.82	[a] Endone [QA]	[a] Mayne Pharma Oxycodone IR [YN]
						[a] Oxycodone Aspen [FM]	

oxycodone hydrochloride 5 mg/5 mL oral liquid, 250 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5190E DP	1	..	..	23.42	24.59	OxyNorm Liquid 5mg/5mL [MF]

▪ OXYCODONE

Caution The risk of drug dependence is high.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note OxyContin modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.

Restricted benefit

Chronic severe disabling pain

Clinical criteria:

The condition must be unresponsive to non-opioid analgesics.

oxycodone hydrochloride 10 mg tablet: modified release, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8385H NP	1	..	..	26.46	27.63	[a] Oxycodone Sandoz [SZ]	[a] OxyContin [MF]

oxycodone hydrochloride 15 mg tablet: modified release, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9399Q NP	1	..	..	32.57	33.74	OxyContin [MF]

oxycodone hydrochloride 20 mg tablet: modified release, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8386J NP	1	..	..	36.59	37.76	[a] Oxycodone Sandoz [SZ]	[a] OxyContin [MF]

oxycodone hydrochloride 30 mg tablet: modified release, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9400R NP	1	..	..	46.15	38.30	OxyContin [MF]

oxycodone hydrochloride 40 mg tablet: modified release, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8387K NP	1	..	..	54.17	38.30	[a] Oxycodone Sandoz [SZ]	[a] OxyContin [MF]

oxycodone hydrochloride 80 mg tablet: modified release, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8388L NP	1	..	..	80.22	38.30	[a] Oxycodone Sandoz [SZ]	[a] OxyContin [MF]

▪ OXYCODONE + NALOXONE

Caution The risk of drug dependence is high.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical

practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Chronic severe disabling pain

Clinical criteria:

The condition must be unresponsive to non-opioid analgesics.

oxycodone hydrochloride 10 mg + naloxone hydrochloride 5 mg tablet: modified release, 28

8934F (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	32.06	33.23	Targin 10/5mg [MF]

oxycodone hydrochloride 15 mg + naloxone hydrochloride 7.5 mg tablet: modified release, 28 tablets

10757E (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	36.41	37.58	Targin 15/7.5mg [MF]

oxycodone hydrochloride 2.5 mg + naloxone hydrochloride 1.25 mg tablet: modified release, 28 tablets

10776E (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	23.19	24.36	Targin 2.5/1.25 mg [MF]

oxycodone hydrochloride 20 mg + naloxone hydrochloride 10 mg tablet: modified release, 28

8935G (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	46.55	38.30	Targin 20/10mg [MF]

oxycodone hydrochloride 30 mg + naloxone hydrochloride 15 mg tablet: modified release, 28 tablets

10758F (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	52.70	38.30	Targin 30/15 mg [MF]

oxycodone hydrochloride 40 mg + naloxone hydrochloride 20 mg tablet: modified release, 28

8936H (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	71.65	38.30	Targin 40/20mg [MF]

oxycodone hydrochloride 5 mg + naloxone hydrochloride 2.5 mg tablet: modified release, 28

8000C (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	30.93	32.10	Targin 5/2.5mg [MF]

▪ PARACETAMOL + CODEINE

CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20

3316M (DP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	11.22	12.39	[a] APO- Paracetamol/Codeine 500/30 [TX]	[a] Codalgin Forte [FM]
					[a] Comfarol Forte [SZ]	[a] Paracetamol/Codeine GH 500/30 [GQ]
					[a] Prodeine Forte [AV]	
		[B]0.19	11.41	12.39	[a] Codapane Forte [AL]	
		[B]2.09	13.31	12.39	[a] Panadeine Forte [SW]	

▪ PARACETAMOL + CODEINE

Note Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of codeine phosphate with paracetamol.

CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20

1215Y (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	11.22	12.39	[a] APO- Paracetamol/Codeine 500/30 [TX]	[a] Codalgin Forte [FM]
					[a] Comfarol Forte [SZ]	[a] Paracetamol/Codeine GH 500/30 [GQ]
					[a] Prodeine Forte [AV]	
		[B]0.19	11.41	12.39	[a] Codapane Forte [AL]	
		[B]2.09	13.31	12.39	[a] Panadeine Forte [SW]	

▪ PARACETAMOL + CODEINE

Note Each authority approval will be limited to no more than 240 tablets per month for no more than 6 months.

Authority required

Severe disabling pain

Clinical criteria:

The condition must be unresponsive to non-opioid analgesics.

CODEINE PHOSPHATE with PARACETAMOL Tablet 30 mg-500 mg, 20

8785J (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	..	..	*12.81	13.98	[a] APO- Paracetamol/Codeine 500/30 [TX]	[a] Codalgin Forte [FM]
					[a] Comfarol Forte [SZ]	[a] Paracetamol/Codeine GH 500/30 [GQ]
					[a] Prodeine Forte [AV]	
		[B]0.57	*13.38	13.98	[a] Codapane Forte [AL]	
		[B]6.27	*19.08	13.98	[a] Panadeine Forte [SW]	

Phenylpiperidine derivatives

▪ FENTANYL

Caution The risk of drug dependence is high.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).

Note Pharmaceutical benefits that have the form fentanyl 12 microgram/hour patch are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form fentanyl 25 microgram/hour patch are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form fentanyl 50 microgram/hour patch are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form fentanyl 75 microgram/hour patch are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form fentanyl 100 microgram/hour patch are equivalent for the purposes of substitution.

Restricted benefit

Chronic severe disabling pain

Clinical criteria:

The condition must be unresponsive to non-opioid analgesics.

fentanyl 100 microgram/hour patch, 5

5280X (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	58.98	38.30	[a] Denpax [AF]

fentanyl 100 microgram/hour patch, 5

5441J (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	58.98	38.30	[a] Dutran 100 [EA]	[a] Fenpatch 100 [ZP]

fentanyl 100 microgram/hour patch, 5

8894D (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	58.98	38.30	[a] Durogesic 100 [JC]	[a] Fentanyl Sandoz [SZ]

fentanyl 12 microgram/hour patch, 5

5265D (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	24.81	25.98	[a] Denpax [AF]

fentanyl 12 microgram/hour patch, 5

5437E (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	24.81	25.98	[a] Dutran 12 [EA]	[a] Fenpatch 12 [ZP]

fentanyl 12 microgram/hour patch, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8878G NP	1	..	..	24.81	25.98	[a] Durogesic 12 [JC]	[a] Fentanyl Sandoz [SZ]

fentanyl 25 microgram/hour patch, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5277R NP	1	..	..	27.94	29.11	[a] Denpax [AF]

fentanyl 25 microgram/hour patch, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5438F NP	1	..	..	27.94	29.11	[a] Dutran 25 [EA]	[a] Fenpatch 25 [ZP]

fentanyl 25 microgram/hour patch, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8891Y NP	1	..	..	27.94	29.11	[a] Durogesic 25 [JC]	[a] Fentanyl Sandoz [SZ]

fentanyl 50 microgram/hour patch, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5278T NP	1	..	..	40.18	38.30	[a] Denpax [AF]

fentanyl 50 microgram/hour patch, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5439G NP	1	..	..	40.18	38.30	[a] Dutran 50 [EA]	[a] Fenpatch 50 [ZP]

fentanyl 50 microgram/hour patch, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8892B NP	1	..	..	40.18	38.30	[a] Durogesic 50 [JC]	[a] Fentanyl Sandoz [SZ]

fentanyl 75 microgram/hour patch, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5279W NP	1	..	..	50.11	38.30	[a] Denpax [AF]

fentanyl 75 microgram/hour patch, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5440H NP	1	..	..	50.11	38.30	[a] Dutran 75 [EA]	[a] Fenpatch 75 [ZP]

fentanyl 75 microgram/hour patch, 5

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8893C NP	1	..	..	50.11	38.30	[a] Durogesic 75 [JC]	[a] Fentanyl Sandoz [SZ]

Diphenylpropylamine derivatives

▪ METHADONE

Caution The risk of drug dependence is high.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Severe disabling pain

Clinical criteria:

The condition must be unresponsive to non-opioid analgesics.

methadone hydrochloride 10 mg tablet, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1609Q NP	1	..	..	18.63	19.80	Physeptone [QA]

methadone hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1606M NP	1	..	..	49.01	38.30	Physeptone [QA]

Oripavine derivatives

▪ BUPRENORPHINE

Caution The risk of drug dependence is high.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or
(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Chronic severe disabling pain

Clinical criteria:

The condition must be unresponsive to non-opioid analgesics.

buprenorphine 10 microgram/hour patch, 2

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8866P NP	1	..	..	39.47	38.30	Norspan [MF]

buprenorphine 15 microgram/hour patch, 2

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10770W NP	1	..	..	46.56	38.30	Norspan [MF]

buprenorphine 20 microgram/hour patch, 2

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8867Q NP	1	..	..	53.66	38.30	Norspan [MF]

buprenorphine 25 microgram/hour patch, 2

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10756D NP	1	..	..	60.38	38.30	Norspan [MF]

buprenorphine 30 microgram/hour patch, 2

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10755C NP	1	..	..	67.10	38.30	Norspan [MF]

buprenorphine 40 microgram/hour patch, 2

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10746N NP	1	..	..	80.54	38.30	Norspan [MF]

buprenorphine 5 microgram/hour patch, 2

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8865N NP	1	..	..	27.85	29.02	Norspan [MF]

Other opioids

▪ TAPENTADOL

Caution The risk of drug dependence is high.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or

(iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or
(iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.

Restricted benefit

Chronic severe disabling pain

Clinical criteria:

The condition must be unresponsive to non-opioid analgesics.

tapentadol 100 mg tablet: modified release, 28

10094G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	32.62	33.79	Palexia SR [CS]

tapentadol 150 mg tablet: modified release, 28

10100N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	40.18	38.30	Palexia SR [CS]

tapentadol 200 mg tablet: modified release, 28

10091D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	46.85	38.30	Palexia SR [CS]

tapentadol 250 mg tablet: modified release, 28

10092E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	52.51	38.30	Palexia SR [CS]

tapentadol 50 mg tablet: modified release, 28

10096J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	24.75	25.92	Palexia SR [CS]

▪ TRAMADOL

Restricted benefit

Pain

Clinical criteria:

The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

tramadol hydrochloride 100 mg/mL oral liquid, 10 mL

5150C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	‡1	..	..	16.76	17.93	Tramal [CS]

▪ TRAMADOL

Restricted benefit

Acute pain

Clinical criteria:

The treatment must be for the short-term.

tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules

5231H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	13.98	15.15	[a] Tramadol ACT [EA] [a] Tramal 100 [CS]	[a] Tramadol Sandoz [SZ]

▪ TRAMADOL

Note Authorities for increased maximum quantities and/or repeats will be granted only for severe disabling pain not responding to non-opioid analgesics.

Restricted benefit

Pain

Clinical criteria:

The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

tramadol hydrochloride 100 mg tablet: modified release, 20

8523N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	13.14	14.31	[a] APO-Tramadol SR [TX] [a] GA Tramadol SR 100mg [ED] [a] Terry White Chemists Tramadol SR [TW]	[a] Chem mart Tramadol SR [CH] [a] Lodam SR 100 [ZP] [a] Tramadol AN SR [EA]

						[a] Tramadol Sandoz SR [SZ]	[a] Tramadol SR generichealth [GQ]
						[a] Tramedo SR 100 [AF]	[a] Zydol SR 100 [RW]
			[B]4.49	17.63	14.31	[a] Tramal SR 100 [CS]	

tramadol hydrochloride 100 mg/mL oral liquid, 10 mL

8843K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	..	..	16.76	17.93	Tramal [CS]

tramadol hydrochloride 150 mg tablet: modified release, 20

8524P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	14.08	15.25	[a] APO-Tramadol SR [TX]	[a] Chem mart Tramadol SR [CH]
						[a] GA Tramadol SR 150mg [ED]	[a] Lodam SR 150 [ZP]
						[a] Terry White Chemists Tramadol SR [TW]	[a] Tramadol AN SR [EA]
						[a] Tramadol Sandoz SR [SZ]	[a] Tramadol SR generichealth [GQ]
						[a] Tramedo SR 150 [AF]	[a] Zydol SR 150 [RW]
			[B]5.37	19.45	15.25	[a] Tramal SR 150 [CS]	

tramadol hydrochloride 200 mg tablet: modified release, 20

8525Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	14.87	16.04	[a] APO-Tramadol SR [TX]	[a] Chem mart Tramadol SR [CH]
						[a] GA Tramadol SR 200mg [ED]	[a] Terry White Chemists Tramadol SR [TW]
						[a] Tramadol AN SR [EA]	[a] Tramadol Sandoz SR [SZ]
						[a] Tramadol SR generichealth [GQ]	[a] Tramedo SR 200 [AF]
						[a] Zydol SR 200 [RW]	
			[B]6.08	20.95	16.04	[a] Tramal SR 200 [CS]	

tramadol hydrochloride 50 mg tablet: modified release, 20

2527B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	13.57	14.74	Tramal SR 50 [CS]

▪ TRAMADOL

Restricted benefit

Acute pain

Clinical criteria:

The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

Restricted benefit

Chronic pain

Treatment Phase: Dose titration

Clinical criteria:

The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

tramadol hydrochloride 50 mg capsule, 20

5232J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	11.42	12.59	[a] APO-Tramadol [TX]	[a] Chem mart Tramadol [CH]
						[a] Terry White Chemists Tramadol [TW]	[a] Tramadol Actavis [ED]
						[a] Tramadol AN [EA]	[a] Tramadol Sandoz [SZ]
						[a] Tramadol SCP [CR]	[a] Tramedo [AF]
						[a] Zydol [RW]	
			[B]2.42	13.84	12.59	[a] Tramal [CS]	

▪ TRAMADOL

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Acute pain

Clinical criteria:

The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

tramadol hydrochloride 50 mg capsule, 20

8455B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	11.42	12.59	[a] APO-Tramadol [TX]	[a] Chem mart Tramadol [CH]
						[a] Terry White Chemists Tramadol [TW]	[a] Tramadol Actavis [ED]

				[a] Tramadol AN [EA]	[a] Tramadol Sandoz [SZ]
				[a] Tramadol SCP [CR]	[a] Tramedo [AF]
				[a] Zydol [RW]	
	[B]2.42	13.84	12.59	[a] Tramal [CS]	

▪ TRAMADOL

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit
Acute pain
Clinical criteria:
The treatment must be for the short-term.

tramadol hydrochloride 100 mg/2 mL injection, 5 x 2 mL ampoules

8582Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	13.98	15.15	[a] Tramadol ACT [EA]	[a] Tramadol Sandoz [SZ]
					[a] Tramal 100 [CS]	

▪ TRAMADOL

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit
Chronic pain
Treatment Phase: Dose titration
Clinical criteria:
The condition must be one in which aspirin and/or paracetamol alone are inappropriate or have failed.

tramadol hydrochloride 50 mg capsule, 20

8611F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	11.42	12.59	[a] APO-Tramadol [TX]	[a] Chem mart Tramadol [CH]
					[a] Terry White Chemists Tramadol [TW]	[a] Tramadol Actavis [ED]
					[a] Tramadol AN [EA]	[a] Tramadol Sandoz [SZ]
					[a] Tramadol SCP [CR]	[a] Tramedo [AF]
					[a] Zydol [RW]	
	[B]2.42	13.84	12.59		[a] Tramal [CS]	

OTHER ANALGESICS AND ANTIPYRETICS

Salicylic acid and derivatives

▪ ASPIRIN

Restricted benefit
For treatment of a patient identifying as Aboriginal or Torres Strait Islander

aspirin 300 mg tablet: effervescent, 96

1010E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	11.94	13.11	Solprin [RC]

▪ ASPIRIN

Restricted benefit
For treatment of a patient identifying as Aboriginal or Torres Strait Islander

aspirin 300 mg tablet: effervescent, 96

5018D DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	11.94	13.11	Solprin [RC]

Anilides

▪ PARACETAMOL

Restricted benefit
For treatment of a patient identifying as Aboriginal or Torres Strait Islander

paracetamol 120 mg/5 mL oral liquid, 100 mL

1747Y NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	12.99	14.16	Panamax [SW]

paracetamol 240 mg/5 mL oral liquid, 200 mL

1770E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	14.12	15.29	Panamax 240 Elixir [SW]

paracetamol 500 mg tablet, 100

1746X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	12.07	13.24	[a] APO-Paracetamol [TX] [a] Generic Health Pty Ltd [GQ] [a] Paracetamol (Sandoz) [SZ] [a] Parapane [AF]	[a] Febridol [EA] [a] Panamax [SW] [a] Paralgin [FM]

▪ PARACETAMOL

Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

paracetamol 120 mg/5 mL oral liquid, 100 mL

3348F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	‡1	..	..	12.99	14.16	Panamax [SW]

paracetamol 240 mg/5 mL oral liquid, 200 mL

3349G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	‡1	..	..	14.12	15.29	Panamax 240 Elixir [SW]

paracetamol 500 mg tablet, 100

5196L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	12.07	13.24	[a] APO-Paracetamol [TX] [a] Generic Health Pty Ltd [GQ] [a] Paracetamol (Sandoz) [SZ] [a] Parapane [AF]	[a] Febridol [EA] [a] Panamax [SW] [a] Paralgin [FM]

▪ PARACETAMOL

Restricted benefit

Persistent pain

Clinical criteria:

The condition must be associated with osteoarthritis.

Population criteria:

Patient must identify as Aboriginal or Torres Strait Islander.

paracetamol 665 mg tablet: modified release, 96

8814X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*17.89	19.06	Osteomol 665 Paracetamol [CR]

▪ PARACETAMOL

Restricted benefit

Chronic arthropathies

Population criteria:

Patient must identify as Aboriginal or Torres Strait Islander.

paracetamol 500 mg tablet, 100

5224Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	3	..	..	*15.36	16.53	[a] APO-Paracetamol [TX] [a] Generic Health Pty Ltd [GQ] [a] Paracetamol (Sandoz) [SZ] [a] Parapane [AF]	[a] Febridol [EA] [a] Panamax [SW] [a] Paralgin [FM]

▪ PARACETAMOL

Restricted benefit

Chronic arthropathies

Population criteria:

Patient must identify as Aboriginal or Torres Strait Islander.

paracetamol 500 mg tablet, 100

8784H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	3	4	..	*15.36	16.53	[a] APO-Paracetamol [TX] [a] Generic Health Pty Ltd [GQ] [a] Paracetamol (Sandoz) [SZ] [a] Parapane [AF]	[a] Febridol [EA] [a] Panamax [SW] [a] Paralgin [FM]

Other analgesics and antipyretics

▪ PREGABALIN

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4172

Neuropathic pain

Clinical criteria:

The condition must be refractory to treatment with other drugs.

pregabalin 150 mg capsule, 56

2355Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	68.48	38.30	Lyrica [PF]

pregabalin 25 mg capsule, 56

2348N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	27.53	28.70	Lyrica [PF]

pregabalin 300 mg capsule, 56

2363J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	97.05	38.30	Lyrica [PF]

pregabalin 75 mg capsule, 56

2335X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	48.27	38.30	Lyrica [PF]

ANTIMIGRAINE PREPARATIONS

Selective serotonin (5HT1) agonists

▪ ELETRIPTAN

Caution Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Migraine attack

Clinical criteria:

The condition must have usually failed to respond to analgesics in the past.

eletriptan 40 mg tablet, 4

5290K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	25.57	26.74	Relpax [PF]

eletriptan 80 mg tablet, 4

5291L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	25.57	26.74	Relpax [PF]

▪ NARATRIPTAN

Caution Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Migraine attack

Clinical criteria:

The condition must have usually failed to respond to analgesics in the past.

naratriptan 2.5 mg tablet, 2

8298R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	[S]2.28	*28.81	27.70	Naramig [AS]

▪ NARATRIPTAN

Caution Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required
Migraine attack
Clinical criteria:
The condition must have usually failed to respond to analgesics in the past, AND
Patient must be one in whom adverse events have occurred with other suitable PBS-listed drugs.

Authority required
Migraine attack
Clinical criteria:
The condition must have usually failed to respond to analgesics in the past, AND
Patient must be one in whom drug interactions have occurred with other suitable PBS-listed drugs.

Authority required
Migraine attack
Clinical criteria:
The condition must have usually failed to respond to analgesics in the past, AND
Patient must be one in whom drug interactions are expected to occur with other suitable PBS-listed drugs.

Authority required
Migraine attack
Clinical criteria:
The condition must have usually failed to respond to analgesics in the past, AND
Patient must be one in whom transfer to another suitable PBS-listed drug would cause patient confusion resulting in problems with compliance.

Authority required
Migraine attack
Clinical criteria:
The condition must have usually failed to respond to analgesics in the past, AND
Patient must be one in whom transfer to another suitable PBS-listed drug is likely to result in adverse clinical consequences.

naratriptan 2.5 mg tablet, 2

9734H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*28.81	29.98	Naramig [AS]

▪ RIZATRIPTAN

Caution Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Pharmaceutical benefits that have the form rizatriptan wafer 10 mg (as benzoate) and pharmaceutical benefits that have the form rizatriptan tablet (orally disintegrating) 10 mg (as benzoate) are equivalent for the purposes of substitution.

Restricted benefit
Migraine attack
Clinical criteria:
The condition must have usually failed to respond to analgesics in the past.

rizatriptan 10 mg tablet: orally disintegrating, 2

10551H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*24.09	25.26	[a] APO-Rizatriptan [TX] [a] Rizatriptan AN ODT [EA] [a] Terry White Chemists Rizatriptan [TW]	[a] Chem mart Rizatriptan [CH] [a] Rizatriptan ODT GH [GQ]

rizatriptan 10 mg wafer, 2

9313E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*24.09	25.26	[a] Maxalt [MK]	[a] Rizatriptan Wafers-10mg [AF]

▪ SUMATRIPTAN

Caution Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Pharmaceutical benefits that have the form sumatriptan tablet 50 mg (as succinate) and pharmaceutical benefits that have the form sumatriptan tablet (fast disintegrating) 50 mg (as succinate) are equivalent for the purposes of substitution.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Migraine attack

Clinical criteria:

The condition must have usually failed to respond to analgesics in the past.

SUMATRIPTAN Tablet (fast disintegrating) 50 mg (as succinate), 2

8885P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	[B]3.56	*20.91	18.52	[a] Imigran FDT [AS]

SUMATRIPTAN Tablet 50 mg (as succinate), 2

8144P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*17.35	18.52	[a] APO-Sumatriptan [TX] [a] Iptam [AL] [a] Sumatran [OW] [a] Terry White Chemists Sumatriptan [TW]	[a] Chem mart Sumatriptan [CH] [a] Sumagran Aspen 50 [RW] [a] Sumatriptan Sandoz [SZ]
			[B]3.56	*20.91	18.52	[a] Imigran [LN]	

SUMATRIPTAN Tablet 50 mg (base) (fast disintegrating), 4

10694W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	[B]3.56	20.90	18.51	[a] Imigran FDT [AS]

sumatriptan 20 mg/actuation nasal spray, 2 actuations

8341B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	21.58	22.75	Imigran [AS]

sumatriptan 50 mg tablet, 4

1849H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.34	18.51	[a] APO-Sumatriptan [TX] [a] Iptam [AL] [a] Sumatran [OW] [a] Sumatriptan-GA [ED] [a] Sumatriptan RBX [RA] [a] Terry White Chemists Sumatriptan [TW]	[a] Chem mart Sumatriptan [CH] [a] Pharmacor Sumatriptan 50 [CR] [a] Sumatriptan AN [EA] [a] Sumatriptan generichealth [GQ] [a] Sumatriptan Sandoz [SZ]
			[B]3.56	20.90	18.51	[a] Imigran [LN]	

▪ ZOLMITRIPTAN

Caution Selective serotonin (5HT1) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Migraine attack

Clinical criteria:

The condition must have usually failed to respond to analgesics in the past.

zolmitriptan 2.5 mg tablet, 2

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8266C NP	2	5	..	*25.57	26.74	[a] APO-Zolmitriptan [TX]	[a] Zoltrip [RW]
			[B]2.76	*28.33	26.74	[a] Zomig [AP]	

Other antimigraine preparations

▪ CYPROHEPTADINE

Note Cyproheptadine hydrochloride is not PBS-subsidised for use in hay fever or atopy.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Prevention of migraine

cyproheptadine hydrochloride 4 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1798P NP	1	2	..	16.85	18.02	Periactin [AS]

▪ PIZOTIFEN

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

pizotifen 500 microgram tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3074T NP	1	2	..	23.09	24.26	Sandomigran 0.5 [NV]

▪ ANTIEPILEPTICS

ANTIEPILEPTICS

Barbiturates and derivatives

▪ PHENOBARBITONE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Epilepsy

phenobarbitone 30 mg tablet, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1850J NP	1	4	..	18.83	20.00	Phenobarbitone Aspen [RW]

phenobarbitone sodium 219 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2138M NP	1	..	..	37.35	38.30	Fawns and McAllan Proprietary Limited [FM]

▪ PRIMIDONE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

primidone 250 mg tablet, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1939C NP	1	2	..	76.97	38.30	Mysoline [LM]

Hydantoin derivatives

▪ PHENYTOIN

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

phenytoin 30 mg/5 mL oral liquid, 500 mL

2692Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	3	..	30.14	31.31	Dilantin [PF]

phenytoin 50 mg tablet: chewable, 200

1249R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	47.82	38.30	Dilantin Infatabs [PF]

phenytoin sodium 100 mg capsule, 200

1874P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	34.18	35.35	Dilantin Sodium [PF]

phenytoin sodium 30 mg capsule, 200

1873N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	30.41	31.58	Dilantin Sodium [PF]

Succinimide derivatives

▪ ETHOSUXIMIDE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

ethosuximide 250 mg capsule, 200

1413J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	75.60	38.30	Zarontin [PF]

ethosuximide 250 mg/5 mL oral liquid, 200 mL

1414K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	29.14	30.31	Zarontin [PF]

Benzodiazepine derivatives

▪ CLONAZEPAM

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Epilepsy

clonazepam 1 mg/mL injection [5 x 1 mL ampoules] (&) inert substance diluent [5 x 1 mL ampoules], 1 pack

1807D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	20.99	22.16	Rivotril [RO]

▪ CLONAZEPAM

Caution Abuse of clonazepam has been reported. Refer to the current product information.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required
Neurologically proven epilepsy

clonazepam 2 mg tablet, 100

1806C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	2	..	*31.85	33.02	[a] Paxam 2 [AF]
			[B]3.36	*35.21	33.02	[a] Rivotril [RO]

clonazepam 2.5 mg/mL oral liquid, 10 mL

1808E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*17.93	19.10	Rivotril [RO]

clonazepam 500 microgram tablet, 100

1805B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	2	..	*21.81	22.98	[a] Paxam 0.5 [AF]
			[B]2.96	*24.77	22.98	[a] Rivotril [RO]

▪ NITRAZEPAM

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required
Myoclonic epilepsy
Authority required
Malignant neoplasia (late stage)
Authority required
Insomnia
Clinical criteria:
Patient must be receiving this drug for the management of insomnia, AND
Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, AND
Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.
Authority required
Insomnia
Clinical criteria:
Patient must be receiving this drug for the management of insomnia, AND
Patient must be receiving long-term nursing care, AND
Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, AND
Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

nitrazepam 5 mg tablet, 25

2732T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*13.65	14.82	[a] Alodorm [AF]
			[B]2.48	*16.13	14.82	[a] Mogadon [IA]

Carboxamide derivatives

▪ CARBAMAZEPINE

CARBAMAZEPINE Tablet 100 mg, 100

5039F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	2	..	..	*20.93	22.10	[a] Carbamazepine Sandoz [SZ]
			[B]2.96	*23.89	22.10	[a] Tegretol 100 [NV]

carbamazepine 100 mg/5 mL oral liquid, 300 mL

5041H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	‡1	..	..	23.40	24.57	Tegretol Liquid [NV]

carbamazepine 200 mg tablet: modified release, 200

5038E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	30.47	31.64	Tegretol CR 200 [NV]

carbamazepine 400 mg tablet: modified release, 200

5037D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	48.53	38.30	Tegretol CR 400 [NV]

▪ CARBAMAZEPINE

Note For item codes 5040G and 1724R, pharmaceutical benefits that have the form tablet 200 mg are equivalent for the purposes of substitution

CARBAMAZEPINE Tablet 200 mg, 100

1724R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	2	..	..	*30.07	31.24	[a] Carbamazepine Sandoz [SZ]
			[B]2.96	*33.03	31.24	[a] Tegretol 200 [NV]

carbamazepine 200 mg tablet, 200

5040G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	30.05	31.22	[a] Teril [AF]

▪ CARBAMAZEPINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

CARBAMAZEPINE Tablet 100 mg, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2422L NP	2	2	..	*20.93	22.10	[a] Carbamazepine Sandoz [SZ]
			[B]2.96	*23.89	22.10	[a] Tegretol 100 [NV]

carbamazepine 100 mg/5 mL oral liquid, 300 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2427R NP	‡1	5	..	23.40	24.57	Tegretol Liquid [NV]

carbamazepine 200 mg tablet: modified release, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2426Q NP	1	2	..	30.47	31.64	Tegretol CR 200 [NV]

carbamazepine 400 mg tablet: modified release, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2431Y NP	1	2	..	48.53	38.30	Tegretol CR 400 [NV]

▪ CARBAMAZEPINE

Note For item codes 2419H and 1706T, pharmaceutical benefits that have the form tablet 200 mg are equivalent for the purposes of substitution.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

CARBAMAZEPINE Tablet 200 mg, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1706T NP	2	2	..	*30.07	31.24	[a] Carbamazepine Sandoz [SZ]
			[B]2.96	*33.03	31.24	[a] Tegretol 200 [NV]

carbamazepine 200 mg tablet, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2419H NP	1	2	..	30.05	31.22	[a] Teril [AF]

▪ OXCARBAZEPINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
5183
Seizures
Clinical criteria:
Patient must have partial epileptic seizures; OR
Patient must have partial epileptic seizures; OR
Patient must have primary generalised tonic-clonic seizures; OR
Patient must have primary generalised tonic-clonic seizures, AND
The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

oxcarbazepine 150 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8584T NP	1	5	..	67.29	38.30	Trileptal [NV]

oxcarbazepine 300 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8585W NP	1	5	..	104.26	38.30	Trileptal [NV]

oxcarbazepine 60 mg/mL oral liquid, 250 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8588B NP	2	5	..	*124.17	38.30	Trileptal [NV]

oxcarbazepine 600 mg tablet, 100

8586X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	167.22	38.30	Trileptal [NV]

Fatty acid derivatives

▪ TIAGABINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
4928
Partial epileptic seizures
Clinical criteria:
The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

tiagabine 10 mg tablet, 50

8222R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*124.79	38.30	Gabitril [OA]

tiagabine 15 mg tablet, 50

8223T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*174.91	38.30	Gabitril [OA]

tiagabine 5 mg tablet, 50

8221Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*67.61	38.30	Gabitril [OA]

▪ VALPROATE

Caution There are reports of fatal hepatotoxicity, particularly in children.
There is increasing evidence of dose-related teratogenesis from this drug.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

valproate sodium 100 mg tablet, 100

2294R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	2	..	*32.67	33.84	Epilim [SW]

valproate sodium 200 mg tablet: enteric, 100

2289L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*24.19	25.36	[a] Sodium Valproate Sandoz [SZ] [a] Valpro 200 [AF]	[a] Valprease 200 [RW] [a] Valproate Winthrop EC 200 [WA]
			[B]2.00	*26.19	25.36	[a] Epilim EC [SW]	

valproate sodium 200 mg/5 mL oral liquid, 300 mL

2293Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	2	..	*38.39	38.30	Epilim Liquid [SW]

valproate sodium 200 mg/5 mL oral liquid, 300 mL

2295T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	2	..	*38.39	38.30	Epilim Syrup [SW]

valproate sodium 500 mg tablet: enteric, 100

2290M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*37.67	38.30	[a] Sodium Valproate Sandoz [SZ] [a] Valpro 500 [AF]	[a] Valprease 500 [RW] [a] Valproate Winthrop EC 500 [WA]
			[B]2.00	*39.67	38.30	[a] Epilim EC [SW]	

▪ VIGABATRIN

Caution Visual field defects have been reported with this drug.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4929

Epileptic seizures

Clinical criteria:

The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

vigabatrin 500 mg oral liquid: powder for, 60 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2668K NP	1	5	..	73.23	38.30	Sabril [SW]

vigabatrin 500 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2667J NP	1	5	..	107.46	38.30	Sabril [SW]

Other antiepileptics

▪ GABAPENTIN

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4928

Partial epileptic seizures

Clinical criteria:

The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

gabapentin 100 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8505P NP	1	5	..	15.05	16.22	[a] APO-Gabapentin [TX] [a] Gabapentin Aspen 100 [RW] [a] Nupentin 100 [AF]	[a] Gabacor [CR] [a] Neurontin [PF]

gabapentin 300 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1834M NP	1	5	..	25.89	27.06	[a] Gabacor [CR] [a] Gabapentin GH [GQ] [a] Gantin [EA] [a] Neurontin [PF]	[a] Gabapentin Aspen 300 [RW] [a] Gabapentin Sandoz [SZ] [a] GenRx Gabapentin [GX] [a] Nupentin 300 [AF]

gabapentin 400 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1835N NP	1	5	..	31.52	32.69	[a] Gabacor [CR] [a] Gabapentin GH [GQ] [a] Gantin [EA] [a] Neurontin [PF]	[a] Gabapentin Aspen 400 [RW] [a] Gabapentin Sandoz [SZ] [a] GenRx Gabapentin [GX] [a] Nupentin 400 [AF]

gabapentin 600 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8559L NP	1	5	..	43.91	38.30	[a] Gabapentin AN [EA] [a] Gabaran [RA] [a] Neurontin [PF] [a] Pharmacor Gabapentin 600 [CR]	[a] Gabapentin Aspen 600 [RW] [a] GenRx Gabapentin [GX] [a] Nupentin Tabs [AF]

gabapentin 800 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8389M NP	1	5	..	55.07	38.30	[a] Gabapentin AN [EA] [a] Gabaran [RA] [a] GenRx Gabapentin [GX] [a] Nupentin Tabs [AF]	[a] Gabapentin Aspen 800 [RW] [a] Gantin [ED] [a] Neurontin [PF] [a] Pharmacor Gabapentin 800 [CR]

▪ LACOSAMIDE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4271

Intractable partial epileptic seizures

Treatment Phase: Initial

Clinical criteria:

The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, AND

The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents, AND

The treatment must be for dose titration purposes.

Population criteria:

Patient must be aged 16 years or older.

Treatment criteria:

Must be treated by a neurologist.

lacosamide 100 mg tablet, 14

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9334G NP	1	1	..	49.73	38.30	Vimpat [UC]

lacosamide 150 mg tablet, 14

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9336J NP	1	1	..	69.37	38.30	Vimpat [UC]

lacosamide 50 mg tablet, 14

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9333F NP	1	1	..	30.07	31.24	Vimpat [UC]

▪ LACOSAMIDE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4249

Intractable partial epileptic seizures

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously been treated with PBS-subsidised lacosamide.

Population criteria:

Patient must be aged 16 years or older.

lacosamide 50 mg tablet, 14

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10293R NP	4	5	..	*89.01	38.30	Vimpat [UC]

▪ LACOSAMIDE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4264

Intractable partial epileptic seizures

Treatment Phase: Initial

Clinical criteria:

The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, AND

The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

Population criteria:

Patient must be aged 16 years or older.

Treatment criteria:

Must be treated by a neurologist.

Authority required (STREAMLINED)

4249

Intractable partial epileptic seizures

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously been treated with PBS-subsidised lacosamide.

Population criteria:

Patient must be aged 16 years or older.

lacosamide 100 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9335H NP	1	5	..	167.66	38.30	Vimpat [UC]

▪ LACOSAMIDE

Note No applications for increased maximum quantities will be authorised for the 56 tablet packs of the 150 mg and 200 mg strengths.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4240

Intractable partial epileptic seizures

Treatment Phase: Initial

Clinical criteria:

The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, AND

The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

Population criteria:

Patient must be aged 16 years or older.

Treatment criteria:

Must be treated by a neurologist.

Authority required (STREAMLINED)

4257

Intractable partial epileptic seizures

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously been treated with PBS-subsidised lacosamide.

Population criteria:

Patient must be aged 16 years or older.

lacosamide 150 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9337K NP	1	5	..	248.18	38.30	Vimpat [UC]

lacosamide 200 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9338L NP	1	5	..	329.53	38.30	Vimpat [UC]

▪ LAMOTRIGINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

5138

Epileptic seizures

Clinical criteria:

The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

lamotrigine 100 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2850B NP	1	5	..	29.46	30.63	[a] APO-Lamotrigine [TX] [a] Lamidus [RA] [a] Lamotrigine Aspen 100 [RW] [a] Lamotrigine generichealth [GQ] [a] Lamotrust 100 [CR] [a] Reedos 100 [DO]	[a] GenRx Lamotrigine [GX] [a] Lamotrigine AN [EA] [a] Lamotrigine-GA [ED] [a] Lamotrigine Sandoz [SZ] [a] Logem [AL]

			[B]1.85	31.31	30.63	[a] Lamictal [AS]	

lamotrigine 200 mg tablet, 56

2851C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	42.43	38.30	[a] APO-Lamotrigine [TX] [a] Lamidus [RA] [a] Lamotrigine Aspen 200 [RW] [a] Lamotrigine generichealth [GQ] [a] Lamotrust 200 [CR] [a] Reedos 200 [DO]	[a] GenRx Lamotrigine [GX] [a] Lamotrigine AN [EA] [a] Lamotrigine-GA [ED] [a] Lamotrigine Sandoz [SZ] [a] Logem [AL]
			[B]1.85	44.28	38.30	[a] Lamictal [AS]	

lamotrigine 25 mg tablet, 56

2848X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.28	18.45	[a] APO-Lamotrigine [TX] [a] Lamidus [RA] [a] Lamotrigine Aspen 25 [RW] [a] Lamotrigine generichealth [GQ] [a] Lamotrust 25 [CR] [a] Reedos 25 [DO]	[a] GenRx Lamotrigine [GX] [a] Lamotrigine AN [EA] [a] Lamotrigine-GA [ED] [a] Lamotrigine Sandoz [SZ] [a] Logem [AL]
			[B]1.99	19.27	18.45	[a] Lamictal [AS]	

lamotrigine 5 mg tablet, 56

8063J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	14.29	15.46	[a] Lamotrigine Aspen 5 [RW]
			[B]1.72	16.01	15.46	[a] Lamictal [AS]

lamotrigine 50 mg tablet, 56

2849Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.86	23.03	[a] APO-Lamotrigine [TX] [a] Lamidus [RA] [a] Lamotrigine Aspen 50 [RW] [a] Lamotrigine generichealth [GQ] [a] Lamotrust 50 [CR] [a] Reedos 50 [DO]	[a] GenRx Lamotrigine [GX] [a] Lamotrigine AN [EA] [a] Lamotrigine-GA [ED] [a] Lamotrigine Sandoz [SZ] [a] Logem [AL]
			[B]1.77	23.63	23.03	[a] Lamictal [AS]	

▪ LEVETIRACETAM

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
4928
Partial epileptic seizures
Clinical criteria:
The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

levetiracetam 1 g tablet, 60

8656N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	62.48	38.30	[a] APO-Levetiracetam [TX] [a] Kepcet [ED] [a] Kerron 1000 [DO] [a] Levactam [ER] [a] Levetiracetam AN [EA] [a] Levetiracetam SZ [SZ] [a] Levitaccord [RA]	[a] Chem mart Levetiracetam [CH] [a] Keppra [UC] [a] Kevtam [AF] [a] Levecetam 1000 [RZ] [a] Levetiracetam generichealth [GQ] [a] Levi 1000 [RW] [a] Terry White Chemists Levetiracetam [TW]

levetiracetam 250 mg tablet, 60

8654L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	29.17	30.34	[a] APO-Levetiracetam [TX] [a] Kepcet [ED] [a] Kerron 250 [DO] [a] Levactam [ER]	[a] Chem mart Levetiracetam [CH] [a] Keppra [UC] [a] Kevtam [AF] [a] Levecetam 250 [RZ]

					[a] Levetiracetam AN [EA]	[a] Levetiracetam generichealth [GQ]
					[a] Levetiracetam SZ [SZ]	[a] Levi 250 [RW]
					[a] Levitaccord [RA]	[a] Terry White Chemists Levetiracetam [TW]

levetiracetam 500 mg tablet, 60

8655M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	41.67	38.30	[a] APO-Levetiracetam [TX]	[a] Chem mart Levetiracetam [CH]
						[a] Kepcet [ED]	[a] Keppra [UC]
						[a] Kerron 500 [DO]	[a] Kevtam [AF]
						[a] Levactam [ER]	[a] Levecetam 500 [RZ]
						[a] Levetiracetam AN [EA]	[a] Levetiracetam GH [GQ]
						[a] Levetiracetam SZ [SZ]	[a] Levi 500 [RW]
						[a] Levitaccord [RA]	[a] Terry White Chemists Levetiracetam [TW]

▪ LEVETIRACETAM

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

5215

Partial epileptic seizures

Clinical criteria:

The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, AND

Patient must be unable to take a solid dose form of levetiracetam.

levetiracetam 100 mg/mL oral liquid, 300 mL

9169N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	5	..	72.78	38.30	[a] Keppra [UC]	[a] Kerron [DO]
						[a] Levetiracetam-AFT [AE]	

▪ PERAMPANEL

Authority required (STREAMLINED)

4656

Intractable partial epileptic seizures

Treatment Phase: Initial

Clinical criteria:

The treatment must be in combination with two or more anti-epileptic drugs which includes one second-line adjunctive agent, AND

The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, which includes at least one first-line anti-epileptic agent and at least two second-line adjunctive anti-epileptic agents.

Treatment criteria:

Must be treated by a neurologist.

perampanel 2 mg tablet, 7

10157N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	1	..	*51.81	38.30	Fycompa [EI]

▪ PERAMPANEL

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4658

Intractable partial epileptic seizures

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug.

perampanel 10 mg tablet, 28

10151G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	346.66	38.30	Fycompa [EI]

perampanel 12 mg tablet, 28

10159Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	346.66	38.30	Fycompa [EI]

perampanel 4 mg tablets, 28

10162W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	175.91	38.30	Fycompa [EI]

perampanel 6 mg tablet, 28

10163X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	261.05	38.30	Fycompa [EI]

perampanel 8 mg tablet, 28

10160R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	346.66	38.30	Fycompa [EI]

▪ SULTHIAME

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

sulthiame 200 mg tablet, 200

2100M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	182.91	38.30	Ospolot [PL]

sulthiame 50 mg tablet, 200

2099L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	76.10	38.30	Ospolot [PL]

▪ TOPIRAMATE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
5516
Seizures
Clinical criteria:
Patient must have partial epileptic seizures; OR
Patient must have primary generalised tonic-clonic seizures; OR
Patient must have seizures of the Lennox-Gastaut syndrome, AND
The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

topiramate 100 mg tablet, 60

8165R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	39.13	38.30	[a] APO-Topiramate [TX] [a] RBX Topiramate [RA] [a] Topamax [JC] [a] Topiramate GH [GQ]	[a] Epiramax 100 [RW] [a] Tamate [AF] [a] Topiramate AN [EA] [a] Topiramate Sandoz [SZ]

topiramate 200 mg tablet, 60

8166T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	58.66	38.30	[a] APO-Topiramate [TX] [a] RBX Topiramate [RA] [a] Topamax [JC] [a] Topiramate GH [GQ]	[a] Epiramax 200 [RW] [a] Tamate [AF] [a] Topiramate AN [EA] [a] Topiramate Sandoz [SZ]

▪ TOPIRAMATE

Note Continuing Therapy Only:
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Authority required (STREAMLINED)
5173
Seizures

Clinical criteria:
Patient must have partial epileptic seizures; OR
Patient must have primary generalised tonic-clonic seizures; OR
Patient must have seizures of the Lennox-Gastaut syndrome, AND
The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, AND
Patient must be unable to take a solid dose form of topiramate.

topiramate 15 mg capsule, 60

8371N NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	18.51	19.68	Topamax Sprinkle [JC]

topiramate 25 mg capsule, 60

8372P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	21.35	22.52	Topamax Sprinkle [JC]

topiramate 50 mg capsule, 60

8520K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	28.66	29.83	Topamax Sprinkle [JC]

▪ TOPIRAMATE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
5516
Seizures
Clinical criteria:
Patient must have partial epileptic seizures; OR
Patient must have primary generalised tonic-clonic seizures; OR
Patient must have seizures of the Lennox-Gastaut syndrome, AND
The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.
Authority required (STREAMLINED)
5325
Migraine
Clinical criteria:
The treatment must be for prophylaxis, AND
Patient must have experienced an average of 3 or more migraines per month over a period of at least 6 months, AND
Patient must have a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; OR
Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker, AND
Patient must have a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk; OR
Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with pizotifen.
Details of the contraindication and/or intolerance(s) must be documented in the patient's medical records when treatment is initiated.

topiramate 25 mg tablet, 60

8163P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	21.54	22.71	[a] APO-Topiramate [TX]	[a] Epiramax 25 [RW]
					[a] RBX Topiramate [RA]	[a] Tamate [AF]
					[a] Topamax [JC]	[a] Topiramate AN [EA]
					[a] Topiramate GH [GQ]	[a] Topiramate Sandoz [SZ]

topiramate 50 mg tablet, 60

8164Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	28.68	29.85	[a] APO-Topiramate [TX]	[a] Epiramax 50 [RW]
					[a] RBX Topiramate [RA]	[a] Tamate [AF]
					[a] Topamax [JC]	[a] Topiramate AN [EA]
					[a] Topiramate GH [GQ]	[a] Topiramate Sandoz [SZ]

▪ ZONISAMIDE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4928
Partial epileptic seizures
Clinical criteria:
The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

zonisamide 100 mg capsule, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9390F NP	2	5	..	*85.59	38.30	Zonegran [SA]

zonisamide 25 mg capsule, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9388D NP	1	5	..	23.95	25.12	Zonegran [SA]

zonisamide 50 mg capsule, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9389E NP	1	5	..	32.98	34.15	Zonegran [SA]

ANTI-PARKINSON DRUGS

ANTICHOLINERGIC AGENTS

Tertiary amines

BENZHEXOL

benzhexol hydrochloride 2 mg tablet, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1109J NP	1	2	..	17.77	18.94	Artane [RW]

benzhexol hydrochloride 5 mg tablet, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1110K NP	1	1	..	23.30	24.47	Artane [RW]

BIPERIDEN

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

biperiden hydrochloride 2 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2544X NP	2	2	..	*22.39	23.56	Akineton [ZC]

Ethers of tropine or tropine derivatives

BENZTROPINE

benztropine mesylate 2 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2362H NP	1	2	..	17.61	18.78	Benztrop [PL]

benztropine mesylate 2 mg/2 mL injection, 10 x 2 mL vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10013B NP	1	..	..	262.61	38.30	Benztropine Omega [FK]

benztropine mesylate 2 mg/2 mL injection, 10 x 2 mL vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10027R DP	1	..	..	262.61	38.30	Benztropine Omega [FK]

benztropine mesylate 2 mg/2 mL injection, 5 x 2 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3038X NP	1	..	..	94.34	38.30	Cogentin [FK]

benztropine mesylate 2 mg/2 mL injection, 5 x 2 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5031T DP	1	..	..	94.34	38.30	Cogentin [FK]

DOPAMINERGIC AGENTS

Dopa and dopa derivatives

▪ LEVODOPA + BENSERAZIDE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

LEVODOPA with BENSERAZIDE Dispersible tablet 100 mg-25 mg, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8219N NP	1	5	..	37.27	38.30	Madopar Rapid 125 [RO]

LEVODOPA with BENSERAZIDE Dispersible tablet 50 mg-12.5 mg, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8218M NP	1	5	..	24.12	25.29	Madopar Rapid 62.5 [RO]

levodopa 100 mg + benserazide 25 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2225D NP	1	5	..	37.27	38.30	Madopar 125 [RO]

levodopa 100 mg + benserazide 25 mg capsule: modified release, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2231K NP	1	5	..	39.94	38.30	Madopar HBS [RO]

levodopa 100 mg + benserazide 25 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2229H NP	1	5	..	37.27	38.30	Madopar 125 [RO]

levodopa 200 mg + benserazide 50 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2226E NP	1	5	..	47.56	38.30	Madopar [RO]

levodopa 200 mg + benserazide 50 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2228G NP	1	5	..	47.56	38.30	Madopar [RO]

levodopa 50 mg + benserazide 12.5 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2227F NP	1	5	..	24.12	25.29	Madopar 62.5 [RO]

▪ LEVODOPA + CARBIDOPA ANHYDROUS

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

levodopa 100 mg + carbidopa anhydrous 25 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1242J NP	1	5	..	38.13	38.30	[a] Kinson [AF]
			[B]4.85	42.98	38.30	[a] Sinemet 100/25 [MK]

levodopa 250 mg + carbidopa anhydrous 25 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1245M NP	1	5	..	44.59	38.30	Sinemet [MK]

▪ LEVODOPA + CARBIDOPA ANHYDROUS

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Parkinson disease

Clinical criteria:

The condition must be one in which fluctuations in motor function are not adequately controlled by frequent dosing with conventional formulations of levodopa with decarboxylase inhibitor.

levodopa 200 mg + carbidopa anhydrous 50 mg tablet: modified release, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1255C NP	1	5	..	66.28	38.30	Sinemet CR [MK]

▪ LEVODOPA + CARBIDOPA ANHYDROUS

Note Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

5473

Advanced Parkinson disease

Treatment Phase: Maintenance therapy

Clinical criteria:

Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, AND

Patient must have been commenced on treatment in a hospital-based movement disorder clinic.

levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8970D NP	8	5	..	*11682.85	38.30	Duodopa [VE]

▪ LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Parkinson disease

Clinical criteria:

Patient must be being treated with levodopa decarboxylase inhibitor combinations, AND

Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

Restricted benefit

Parkinson disease

Clinical criteria:

Patient must be stabilised on concomitant treatment with levodopa decarboxylase inhibitor combinations and entacapone.

levodopa 100 mg + carbidopa anhydrous 25 mg + entacapone 200 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8798C NP	2	4	..	*332.73	38.30	Stalevo 100/25/200mg [NV]

levodopa 125 mg + carbidopa anhydrous 31.25 mg + entacapone 200 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9345W NP	2	4	..	*345.19	38.30	Stalevo 125/31.25/200mg [NV]

levodopa 150 mg + carbidopa anhydrous 37.5 mg + entacapone 200 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8799D NP	2	4	..	*363.83	38.30	Stalevo 150/37.5/200mg [NV]

levodopa 200 mg + carbidopa anhydrous 50 mg + entacapone 200 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9292C NP	2	4	..	*392.45	38.30	Stalevo 200/50/200mg [NV]

levodopa 50 mg + carbidopa anhydrous 12.5 mg + entacapone 200 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8797B NP	2	4	..	*301.65	38.30	Stalevo 50/12.5/200mg [NV]

levodopa 75 mg + carbidopa anhydrous 18.75 mg + entacapone 200 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9344T NP	2	4	..	*315.35	38.30	Stalevo 75/18.75/200mg [NV]

Adamantane derivatives

▪ AMANTADINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Parkinson disease
Clinical criteria:
The condition must not be drug induced.

amantadine hydrochloride 100 mg capsule, 100

3016R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	42.14	38.30	Symmetrel 100 [NV]

Dopamine agonists

▪ BROMOCRIPTINE

Caution Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Note For item codes 1443Y and 1559C, pharmaceutical benefits that have the form tablet 2.5 mg (base) are equivalent for the purposes of substitution.

Restricted benefit
Acromegaly
Restricted benefit
Parkinson disease
Restricted benefit
Pathological hyperprolactinaemia
Clinical criteria:
Patient must be one in whom surgery is not indicated.
Restricted benefit
Pathological hyperprolactinaemia
Clinical criteria:
Patient must have had surgery for this condition with incomplete resolution.
Restricted benefit
Pathological hyperprolactinaemia
Clinical criteria:
Patient must be one in whom radiotherapy is not indicated.
Restricted benefit
Pathological hyperprolactinaemia
Clinical criteria:
Patient must have had radiotherapy for this condition with incomplete resolution.

bromocriptine 2.5 mg tablet, 30

1443Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*32.17	33.34	[a] Parlodel [NV]

bromocriptine 2.5 mg tablet, 60

1559C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	32.16	33.33	[a] Kripton 2.5 [AF]

▪ CABERGOLINE

Caution Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Parkinson disease

cabergoline 1 mg tablet, 30

8393R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	58.93	38.30	Cabaser [PF]

cabergoline 2 mg tablet, 30

8394T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	75.44	38.30	Cabaser [PF]

▪ PRAMIPEXOLE

Caution Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Parkinson disease

pramipexole hydrochloride monohydrate 1 mg tablet, 100

9153R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	121.69	38.30	[a] APO-Pramipexole [TX] [a] Pramipexole GH [GQ] [a] Simipex 1 [RW]	[a] Pramipexole AN [EA] [a] Sifrol [BY] [a] Simpral [AF]

pramipexole hydrochloride monohydrate 125 microgram tablet, 30

9151P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	14.31	15.48	[a] APO-Pramipexole [TX] [a] Pramipexole GH [GQ] [a] Simipex 0.125 [RW]	[a] Pramipexole AN [EA] [a] Sifrol [BY] [a] Simpral [AF]

pramipexole hydrochloride monohydrate 250 microgram tablet, 100

9152Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	35.91	37.08	[a] APO-Pramipexole [TX] [a] Pramipexole GH [GQ] [a] Simipex 0.25 [RW]	[a] Pramipexole AN [EA] [a] Sifrol [BY] [a] Simpral [AF]

▪ PRAMIPEXOLE

Caution Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.
Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Parkinson disease

pramipexole hydrochloride monohydrate 1.5 mg tablet: modified release, 30

3420B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	56.31	38.30	[a] APO-Pramipexole ER [TX]	[a] Sifrol ER [BY]

pramipexole hydrochloride monohydrate 2.25 mg tablet: modified release, 30

5143Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	79.27	38.30	[a] APO-Pramipexole ER [TX]	[a] Sifrol ER [BY]

pramipexole hydrochloride monohydrate 3 mg tablet: modified release, 30

3421C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	110.56	38.30	[a] APO-Pramipexole ER [TX]	[a] Sifrol ER [BY]

pramipexole hydrochloride monohydrate 3.75 mg tablet: modified release, 30

5145T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	133.51	38.30	[a] APO-Pramipexole ER [TX]	[a] Sifrol ER [BY]

pramipexole hydrochloride monohydrate 375 microgram tablet: modified release, 30

3418X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.09	23.26	[a] APO-Pramipexole ER [TX]	[a] Sifrol ER [BY]

pramipexole hydrochloride monohydrate 4.5 mg tablet: modified release, 30

3422D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	160.64	38.30	[a] APO-Pramipexole ER [TX]	[a] Sifrol ER [BY]

pramipexole hydrochloride monohydrate 750 microgram tablet: modified release, 30

3419Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	33.36	34.53	[a] APO-Pramipexole ER [TX]	[a] Sifrol ER [BY]

▪ PRAMIPEXOLE

Caution Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Note This drug is not PBS-subsidised for Restless Legs Syndrome secondary to other causes

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Primary severe restless legs syndrome

Clinical criteria:

Patient must manifest all 4 diagnostic criteria for Restless Legs Syndrome, AND

Patient must have a baseline International Restless Legs Syndrome Rating Scale (IRLSRS) score greater than or equal to 21 points prior to initiation of pramipexole.

The date and IRLSRS score must be documented in the patient's medical records at the time pramipexole treatment is initiated.

The diagnostic criteria for Restless Legs Syndrome are:

(a) An urge to move the legs usually accompanied or caused by unpleasant sensations in the legs; and

(b) The urge to move or unpleasant sensations begin or worsen during periods of rest or inactivity such as lying or sitting; and

(c) The urge to move or unpleasant sensations are partially or totally relieved by movement, such as walking or stretching, at least as long as the activity continues; and

(d) The urge to move or unpleasant sensations are worse in the evening or night than during the day or only occur during the evening or night.

pramipexole hydrochloride monohydrate 125 microgram tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9393J NP	1	2	..	14.31	15.48	Sifrol [BY]

pramipexole hydrochloride monohydrate 250 microgram tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9394K NP	1	2	..	35.91	37.08	Sifrol [BY]

▪ ROTIGOTINE

Restricted benefit

Parkinson disease

Clinical criteria:

The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

rotigotine 4 mg/24 hours patch, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2384L	1	5	..	96.27	38.30	Neupro [UC]

rotigotine 6 mg/24 hours patch, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2410W	1	5	..	107.84	38.30	Neupro [UC]

▪ ROTIGOTINE

Restricted benefit

Parkinson disease

Clinical criteria:

The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

rotigotine 2 mg/24 hours patch, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2385M	1	5	..	74.81	38.30	Neupro [UC]

Monoamine oxidase B inhibitors

▪ RASAGILINE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Parkinson disease

RASAGILINE Tablet 1 mg (as mesilate), 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1952R NP	1	5	..	115.12	38.30	Azilect [TB]

▪ SELEGILINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Late stage Parkinson disease
Clinical criteria:
The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

selegiline hydrochloride 5 mg tablet, 100

1973W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	52.46	38.30	[a] Eldepryl [AS]	[a] Selgene [AF]

Other dopaminergic agents

▪ ENTACAPONE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Parkinson disease
Clinical criteria:
The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination, AND
Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

entacapone 200 mg tablet, 100

8367J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	4	..	*257.21	38.30	Comtan [NV]

▪ PSYCHOLEPTICS

ANTIPSYCHOTICS

Phenothiazines with aliphatic side-chain

▪ CHLORPROMAZINE

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

chlorpromazine hydrochloride 10 mg tablet, 100

1196Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	14.10	15.27	Largactil [SW]

chlorpromazine hydrochloride 100 mg tablet, 100

1199D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	19.52	20.69	Largactil [SW]

chlorpromazine hydrochloride 25 mg tablet, 100

1197B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	14.61	15.78	Largactil [SW]

chlorpromazine hydrochloride 5 mg/mL oral liquid, 100 mL

1201F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	15.68	16.85	Largactil [SW]

chlorpromazine hydrochloride 50 mg/2 mL injection, 10 x 2 mL ampoules

1195X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	22.03	23.20	Largactil [SW]

Phenothiazines with piperazine structure

▪ FLUPHENAZINE DECANOATE

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

fluphenazine decanoate 12.5 mg/0.5 mL injection, 5 x 0.5 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1046C NP	1	..	..	20.99	22.16	Modecate [BQ]

fluphenazine decanoate 25 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3098C NP	1	..	..	26.91	28.08	Modecate [BQ]

fluphenazine decanoate 50 mg/2 mL injection, 5 x 2 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1001Q NP	1	..	..	36.22	37.39	Modecate [BQ]

▪ TRIFLUOPERAZINE

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

trifluoperazine 1 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2185B NP	1	5	..	18.75	19.92	Stelazine [GH]

trifluoperazine 2 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2386N NP	1	5	..	22.83	24.00	Stelazine [GH]

trifluoperazine 5 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2186C NP	1	5	..	24.55	25.72	Stelazine [GH]

Phenothiazines with piperidine structure

▪ PERICYAZINE

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

pericyazine 10 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3053Q NP	1	5	..	17.68	18.85	Neulactil [SW]

pericyazine 2.5 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3052P NP	1	5	..	13.95	15.12	Neulactil [SW]

Butyrophenone derivatives

▪ HALOPERIDOL

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

haloperidol 1.5 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2767P NP	1	5	..	14.13	15.30	Serenace [QA]

haloperidol 2 mg/mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2763K NP	‡1	5	..	22.01	23.18	Serenace [QA]

haloperidol 5 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2770T NP	1	5	..	13.94	15.11	Serenace [QA]

haloperidol 5 mg/mL injection, 10 x 1 mL ampoules

2768Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	23.53	24.70	Serenace [QA]

haloperidol 500 microgram tablet, 100

2761H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	13.84	15.01	Serenace [QA]

▪ HALOPERIDOL DECANOATE

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

haloperidol (as decanoate) 150 mg/3 mL injection, 5 x 3 mL ampoules

2766N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	49.00	38.30	Haldol decanoate [JC]

haloperidol (as decanoate) 50 mg/mL injection, 5 x 1 mL vials

2765M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	29.67	30.84	Haldol decanoate [JC]

Indole derivatives

▪ LURASIDONE

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
4246
Schizophrenia

lurasidone hydrochloride 40 mg tablet, 30

10526B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	77.05	38.30	Latuda [SE]

lurasidone hydrochloride 80 mg tablet, 30

10529E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	143.68	38.30	Latuda [SE]

▪ ZIPRASIDONE

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
4246
Schizophrenia
Authority required (STREAMLINED)
5742
Acute mania or mixed episodes
Clinical criteria:
The condition must be associated with bipolar I disorder, AND
The treatment must be as monotherapy, AND
The treatment must be limited to up to 6 months per episode.

ziprasidone 20 mg capsule, 60

9070J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	64.32	38.30	[a] APO-Ziprasidone [TX]	[a] Zeldox [PF]

ziprasidone 40 mg capsule, 60

9071K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	118.40	38.30	[a] APO-Ziprasidone [TX]	[a] Zeldox [PF]

ziprasidone 60 mg capsule, 60

9072L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	171.82	38.30	[a] APO-Ziprasidone [TX]	[a] Zeldox [PF]

ziprasidone 80 mg capsule, 60

9073M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	227.14	38.30	[a] APO-Ziprasidone [TX]	[a] Zeldox [PF]

Thioxanthene derivatives

▪ FLUPENTHIXOL DECANOATE

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

flupenthixol decanoate 100 mg/mL injection, 5 x 1 mL ampoules

2257T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	45.90	38.30	Fluanxol Concentrated Depot [LU]

flupenthixol decanoate 20 mg/mL injection, 5 x 1 mL ampoules

2255Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	22.05	23.22	Fluanxol Depot [LU]

▪ ZUCLOPENTHIXOL DECANOATE

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

zuclopenthixol decanoate 200 mg/mL injection, 5 x 1 mL ampoules

8097E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	28.52	29.69	Clopixol Depot [LU]

Diazepines, oxazepines, thiazepines and oxepines

▪ ASENAPINE

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
4246
Schizophrenia
Authority required (STREAMLINED)
5773
Acute mania or mixed episodes
Clinical criteria:
The condition must be associated with bipolar I disorder, AND
The treatment must be limited to up to 6 months per episode.
Authority required (STREAMLINED)
5719
Bipolar I disorder
Clinical criteria:
The treatment must be maintenance therapy, AND
The treatment must be as monotherapy.

asenapine 10 mg wafer: sublingual, 60

5141N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	240.41	38.30	Saphris [LU]

asenapine 5 mg wafer: sublingual, 60

5140M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	147.37	38.30	Saphris [LU]

▪ OLANZAPINE

Caution Monitor for post-injection syndrome for at least two hours after each injection.

Note Special Pricing Arrangements apply.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4304

Schizophrenia

olanzapine 210 mg injection: modified release [1 vial] (&) inert substance diluent [3 mL vial], 1 pack

9294E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*495.11	38.30	Zyprexa Relprevv [LY]

olanzapine 300 mg injection: modified release [1 vial] (&) inert substance diluent [3 mL vial], 1 pack

9295F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*803.09	38.30	Zyprexa Relprevv [LY]

olanzapine 405 mg injection: modified release [1 vial] (&) inert substance diluent [3 mL vial], 1 pack

9303P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	495.10	38.30	Zyprexa Relprevv [LY]

▪ OLANZAPINE

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Pharmaceutical benefits that have the form olanzapine tablet 2.5 mg and pharmaceutical benefits that have the form olanzapine tablet 2.5 mg (as benzoate) are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form olanzapine tablet 5 mg and pharmaceutical benefits that have the form olanzapine tablet 5 mg (as benzoate) are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form olanzapine tablet 7.5 mg and pharmaceutical benefits that have the form olanzapine tablet 7.5 mg (as benzoate) are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form olanzapine tablet 10 mg and pharmaceutical benefits that have the form olanzapine tablet 10 mg (as benzoate) are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form olanzapine tablet 5 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 5 mg are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form olanzapine tablet 10 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 10 mg are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form olanzapine tablet 15 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 15 mg are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form olanzapine tablet 20 mg (orally disintegrating) and pharmaceutical benefits that have the form olanzapine wafer 20 mg are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

5856

Schizophrenia

Authority required (STREAMLINED)

5869

Bipolar I disorder

Clinical criteria:

The treatment must be maintenance therapy.

OLANZAPINE Tablet 10 mg (orally disintegrating), 28

3382B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	31.01	32.18	[a] APO-Olanzapine ODT [TX]	[a] Chem mart Olanzapine ODT [CH]
					[a] Olanzapine AN ODT [EA]	[a] Olanzapine-GA ODT [ED]
					[a] Olanzapine ODT-DRLA [RZ]	[a] Olanzapine ODT generichealth 10 [GQ]
					[a] Olanzapine RBX ODT [RA]	[a] Olanzapine Sandoz ODT 10 [SZ]
					[a] Ozin ODT 10 [DO]	[a] Terry White Chemists Olanzapine ODT [TW]

OLANZAPINE Tablet 5 mg (orally disintegrating), 28

3381Y NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	20.61	21.78	[a] APO-Olanzapine ODT [TX]	[a] Chem mart Olanzapine ODT [CH]
					[a] Olanzapine AN ODT [EA]	[a] Olanzapine-GA ODT [ED]

						[a] Olanzapine ODT-DRLA [RZ]	[a] Olanzapine ODT generichealth 5 [GQ]
						[a] Olanzapine RBX ODT [RA]	[a] Olanzapine Sandoz ODT 5 [SZ]
						[a] Ozin ODT 5 [DO]	[a] Terry White Chemists Olanzapine ODT [TW]

olanzapine 10 mg tablet, 28

1042W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	
NP	1	5	..	31.01	32.18	[a] Olanzapine generichealth 10 [GQ]	

olanzapine 10 mg tablet, 28

8187X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	31.01	32.18	[a] APO-Olanzapine [TX]	[a] Chem mart Olanzapine [CH]
						[a] Lanzek [EL]	[a] Olanzacor 10 [CR]
						[a] Olanzapine AN [EA]	[a] Olanzapine-DRLA [RZ]
						[a] Olanzapine-GA [ED]	[a] Olanzapine GH [GQ]
						[a] Olanzapine RBX [RA]	[a] Olanzapine Sandoz [SZ]
						[a] Ozin 10 [DO]	[a] Terry White Chemists Olanzapine [TW]
						[a] Zypine [AF]	[a] Zyprexa [LY]

olanzapine 10 mg wafer, 28

8434X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	31.01	32.18	[a] Lanzek Zydis [EL]	[a] Zypine ODT [AF]
						[a] Zyprexa Zydis [LY]	

olanzapine 15 mg tablet, 28

3384D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	41.29	38.30	[a] APO-Olanzapine ODT [TX]	[a] Chem mart Olanzapine ODT [CH]
						[a] Olanzapine AN ODT [EA]	[a] Olanzapine Sandoz ODT 15 [SZ]
						[a] Ozin ODT 15 [DO]	[a] Terry White Chemists Olanzapine ODT [TW]

olanzapine 15 mg wafer, 28

8952E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	41.29	38.30	[a] Zypine ODT [AF]	[a] Zyprexa Zydis [LY]

olanzapine 2.5 mg tablet, 28

1024X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	
NP	1	5	..	15.57	16.74	[a] Olanzapine generichealth 2.5 [GQ]	

olanzapine 2.5 mg tablet, 28

8170B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.57	16.74	[a] APO-Olanzapine [TX]	[a] Chem mart Olanzapine [CH]
						[a] Lanzek [EL]	[a] Olanzacor 2.5 [CR]
						[a] Olanzapine AN [EA]	[a] Olanzapine-DRLA [RZ]
						[a] Olanzapine-GA [ED]	[a] Olanzapine RBX [RA]
						[a] Olanzapine Sandoz [SZ]	[a] Ozin 2.5 [DO]
						[a] Terry White Chemists Olanzapine [TW]	[a] Zypine [AF]
						[a] Zyprexa [LY]	

olanzapine 20 mg tablet, 28

3385E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	51.58	38.30	[a] APO-Olanzapine ODT [TX]	[a] Chem mart Olanzapine ODT [CH]
						[a] Olanzapine AN ODT [EA]	[a] Olanzapine Sandoz ODT 20 [SZ]
						[a] Ozin ODT 20 [DO]	[a] Terry White Chemists Olanzapine ODT [TW]

olanzapine 20 mg wafer, 28

8953F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	51.58	38.30	[a] Zypine ODT [AF]	[a] Zyprexa Zydis [LY]

olanzapine 5 mg tablet, 28

1037N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	20.61	21.78	[a] Olanzapine generichealth 5 [GQ]

olanzapine 5 mg tablet, 28

8185T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.61	21.78	[a] APO-Olanzapine [TX]	[a] Chem mart Olanzapine [CH]
						[a] Lanzek [EL]	[a] Olanzacor 5 [CR]
						[a] Olanzapine AN [EA]	[a] Olanzapine-DRLA [RZ]
						[a] Olanzapine-GA [ED]	[a] Olanzapine GH [GQ]
						[a] Olanzapine RBX [RA]	[a] Olanzapine Sandoz [SZ]
						[a] Ozin 5 [DO]	[a] Terry White Chemists Olanzapine [TW]
						[a] Zypine [AF]	[a] Zyprexa [LY]

olanzapine 5 mg wafer, 28

8433W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.61	21.78	[a] Lanzek Zydis [EL]	[a] Zypine ODT [AF]
						[a] Zyprexa Zydis [LY]	

olanzapine 7.5 mg tablet, 28

1041T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	25.86	27.03	[a] Olanzapine generichealth 7.5 [GQ]

olanzapine 7.5 mg tablet, 28

8186W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	25.86	27.03	[a] APO-Olanzapine [TX]	[a] Chem mart Olanzapine [CH]
						[a] Lanzek [EL]	[a] Olanzacor 7.5 [CR]
						[a] Olanzapine AN [EA]	[a] Olanzapine-DRLA [RZ]
						[a] Olanzapine-GA [ED]	[a] Olanzapine GH [GQ]
						[a] Olanzapine RBX [RA]	[a] Olanzapine Sandoz [SZ]
						[a] Ozin 7.5 [DO]	[a] Terry White Chemists Olanzapine [TW]
						[a] Zypine [AF]	[a] Zyprexa [LY]

▪ QUETIAPINE

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
4246
Schizophrenia
Authority required (STREAMLINED)
5611
Acute mania
Clinical criteria:
The condition must be associated with bipolar I disorder, AND
The treatment must be as monotherapy, AND
The treatment must be limited to up to 6 months per episode.
Authority required (STREAMLINED)
5639
Bipolar I disorder
Clinical criteria:
The treatment must be maintenance therapy.

quetiapine 100 mg tablet, 90

8457D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	43.37	38.30	[a] APO-Quetiapine [TX]	[a] Chem mart Quetiapine [CH]
						[a] Delucon 100 [DO]	[a] Kaptan [ER]
						[a] Pharmacor Quetiapine 100 [CR]	[a] Quetia 100 [RW]
						[a] Quetiaccord [EF]	[a] Quetiapine Actavis 100 [ED]
						[a] Quetiapine AN [EA]	[a] Quetiapine-DRLA [RZ]
						[a] Quetiapine GH 100 [GQ]	[a] Quetiapine RBX [RA]
						[a] Quetiapine Sandoz [SZ]	[a] Seroquel [AP]

						[a] Syquet [AF]	[a] Terry White Chemists Quetiapine [TW]

quetiapine 150 mg tablet: modified release, 60

5458G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	43.37	38.30	Seroquel XR [AP]

quetiapine 200 mg tablet, 60

8458E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	55.32	38.30	[a] APO-Quetiapine [TX] [a] Delucon 200 [DO] [a] Pharmacor Quetiapine 200 [CR] [a] Quetiaccord [EF] [a] Quetiapine AN [EA] [a] Quetiapine GH 200 [GQ] [a] Quetiapine Sandoz [SZ] [a] Syquet [AF]	[a] Chem mart Quetiapine [CH] [a] Kaptan [ER] [a] Quetia 200 [RW] [a] Quetiapine Actavis 200 [ED] [a] Quetiapine-DRLA [RZ] [a] Quetiapine RBX [RA] [a] Seroquel [AP] [a] Terry White Chemists Quetiapine [TW]

quetiapine 200 mg tablet: modified release, 60

9203J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	55.32	38.30	[a] QUETIAPINE-AS XR [RW]	[a] Seroquel XR [AP]

quetiapine 300 mg tablet, 60

8580N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	76.30	38.30	[a] APO-Quetiapine [TX] [a] Delucon 300 [DO] [a] Pharmacor Quetiapine 300 [CR] [a] Quetiaccord [EF] [a] Quetiapine AN [EA] [a] Quetiapine GH 300 [GQ] [a] Quetiapine Sandoz [SZ] [a] Syquet [AF]	[a] Chem mart Quetiapine [CH] [a] Kaptan [ER] [a] Quetia 300 [RW] [a] Quetiapine Actavis 300 [ED] [a] Quetiapine-DRLA [RZ] [a] Quetiapine RBX [RA] [a] Seroquel [AP] [a] Terry White Chemists Quetiapine [TW]

quetiapine 300 mg tablet: modified release, 60

9204K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	76.30	38.30	[a] QUETIAPINE-AS XR [RW]	[a] Seroquel XR [AP]

quetiapine 400 mg tablet: modified release, 60

9205L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	100.23	38.30	[a] QUETIAPINE-AS XR [RW]	[a] Seroquel XR [AP]

quetiapine 50 mg tablet: modified release, 60

9202H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	33.71	34.88	Seroquel XR [AP]

▪ QUETIAPINE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4391

Schizophrenia

Clinical criteria:

The treatment must be for dose titration purposes.

Authority required (STREAMLINED)

4396

Acute mania

Clinical criteria:

The condition must be associated with bipolar I disorder, AND

The treatment must be as monotherapy, AND

The treatment must be for dose titration purposes.

Authority required (STREAMLINED)

4385

Bipolar I disorder

Clinical criteria:

The treatment must be maintenance therapy, AND

The treatment must be for dose titration purposes.

quetiapine 25 mg tablet, 60

8456C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	22.06	23.23	[a] APO-Quetiapine [TX] [a] Delucon 25 [DO] [a] Pharmacor Quetiapine 25 [CR] [a] Quetiaccord [EF] [a] Quetiapine AN [EA] [a] Quetiapine GH 25 [GQ] [a] Quetiapine Sandoz [SZ] [a] Seroquel [AP] [a] Terry White Chemists Quetiapine [TW]	[a] Chem mart Quetiapine [CH] [a] Kaptan [ER] [a] Quetia 25 [RW] [a] Quetiapine Actavis 25 [ED] [a] Quetiapine-DRLA [RZ] [a] Quetiapine RBX [RA] [a] Seronia 25 [RF] [a] Syquet [AF]

Benzamides

▪ AMISULPRIDE

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4246

Schizophrenia

amisulpride 100 mg tablet, 30

8594H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	19.62	20.79	[a] Amisulpride 100 Winthrop [WA] [a] APO-Amisulpride [TX] [a] Sulprix [AF]	[a] Amisulpride Sandoz [SZ] [a] Solian 100 [SW]

amisulpride 100 mg/mL oral liquid, 60 mL

8736T NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*139.81	38.30	Solian Solution [SW]

amisulpride 200 mg tablet, 60

8595J NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	50.05	38.30	[a] Amisulpride 200 Winthrop [WA] [a] APO-Amisulpride [TX] [a] Sulprix [AF]	[a] Amisulpride Sandoz [SZ] [a] Solian 200 [SW]

amisulpride 400 mg tablet, 60

8596K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	82.30	38.30	[a] Amipride 400 [RW] [a] Amisulpride Sandoz [SZ] [a] Solian 400 [SW]	[a] Amisulpride 400 Winthrop [WA] [a] APO-Amisulpride [TX] [a] Sulprix [AF]

Other antipsychotics

▪ ARIPIPRAZOLE

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4246

Schizophrenia

aripiprazole 10 mg tablet, 30

8717T NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	136.37	38.30	Abilify [OS]

aripiprazole 15 mg tablet, 30

8718W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	189.15	38.30	Abilify [OS]

aripiprazole 20 mg tablet, 30

8719X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	229.29	38.30	Abilify [OS]

aripiprazole 30 mg tablet, 30

8720Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	278.51	38.30	Abilify [OS]

aripiprazole 300 mg injection: modified release [1 x 300 mg vial] (&) inert substance diluent [1 vial], 1 pack

10224D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	299.24	38.30	Abilify Maintena [LU]

aripiprazole 400 mg injection: modified release [1 x 400 mg vial] (&) inert substance diluent [1 vial], 1 pack

10219W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	373.03	38.30	Abilify Maintena [LU]

▪ PALIPERIDONE

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
4246
Schizophrenia

paliperidone 100 mg injection: modified release, 1 syringe

5107T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	413.42	38.30	Invega Sustenna [JC]

paliperidone 150 mg injection: modified release, 1 syringe

5109X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	413.42	38.30	Invega Sustenna [JC]

paliperidone 25 mg injection: modified release, 1 syringe

5100K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	134.10	38.30	Invega Sustenna [JC]

paliperidone 3 mg tablet: modified release, 28

9140C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	73.62	38.30	Invega [JC]

paliperidone 50 mg injection: modified release, 1 syringe

5102M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	260.14	38.30	Invega Sustenna [JC]

paliperidone 6 mg tablet: modified release, 28

9141D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	138.10	38.30	Invega [JC]

paliperidone 75 mg injection: modified release, 1 syringe

5103N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	337.17	38.30	Invega Sustenna [JC]

paliperidone 9 mg tablet: modified release, 28

9142E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	202.33	38.30	Invega [JC]

▪ RISPERIDONE

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4246

Schizophrenia

Authority required (STREAMLINED)

5907

Acute mania

Clinical criteria:

The condition must be associated with bipolar I disorder, AND

The treatment must be as adjunctive therapy to mood stabilisers, AND

The treatment must be limited to up to 6 months per episode.

risperidone 1 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3169T NP	1	5	..	20.18	21.35	[a] APO-Risperidone [TX] [a] Rispa [RW] [a] Rispericor 1 [CR] [a] Risperidone AMNEAL [EF] [a] Risperidone generichealth [GQ] [a] Rispernia [ER]	[a] Ozidal [RA] [a] Risperdal [JC] [a] Risperidone Actavis 1 [ED] [a] Risperidone AN [EA] [a] Risperidone Sandoz [SZ] [a] Rixadone [AF]

risperidone 1 mg/mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8100H NP	‡1	5	..	111.88	38.30	Risperdal [JC]

risperidone 2 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3170W NP	1	5	..	32.75	33.92	[a] APO-Risperidone [TX] [a] Rispa [RW] [a] Rispericor 2 [CR] [a] Risperidone AMNEAL [EF] [a] Risperidone generichealth [GQ] [a] Rispernia [ER]	[a] Ozidal [RA] [a] Risperdal [JC] [a] Risperidone Actavis 2 [ED] [a] Risperidone AN [EA] [a] Risperidone Sandoz [SZ] [a] Rixadone [AF]

risperidone 3 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3171X NP	1	5	..	44.85	38.30	[a] APO-Risperidone [TX] [a] Rispa [RW] [a] Rispericor 3 [CR] [a] Risperidone AMNEAL [EF] [a] Risperidone generichealth [GQ] [a] Rispernia [ER]	[a] Ozidal [RA] [a] Risperdal [JC] [a] Risperidone Actavis 3 [ED] [a] Risperidone AN [EA] [a] Risperidone Sandoz [SZ] [a] Rixadone [AF]

risperidone 4 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3172Y NP	1	5	..	56.90	38.30	[a] APO-Risperidone [TX] [a] Rispa [RW] [a] Rispericor 4 [CR] [a] Risperidone AN [EA] [a] Risperidone Sandoz [SZ] [a] Rixadone [AF]	[a] Ozidal [RA] [a] Risperdal [JC] [a] Risperidone AMNEAL [EF] [a] Risperidone generichealth [GQ] [a] Rispernia [ER]

▪ RISPERIDONE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

5916

Severe behavioural disturbances

Clinical criteria:

Patient must have autism, AND

The treatment must be under the supervision of a paediatrician or psychiatrist, AND

The treatment must be in combination with non-pharmacological measures.

Population criteria:

Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders.

Authority required (STREAMLINED)

5898

Severe behavioural disturbances

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have autism, AND

Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, AND

The treatment must be under the supervision of a paediatrician or psychiatrist, AND

The treatment must be in combination with non-pharmacological measures.

Population criteria:

Patient must be aged 18 years or older.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders.

risperidone 2 mg tablet, 60

9079W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	32.75	33.92	[a] APO-Risperidone [TX]	[a] Ozidal [RA]
						[a] Rispa [RW]	[a] Risperdal [JC]
						[a] Rispericor 2 [CR]	[a] Risperidone Actavis 2 [ED]
						[a] Risperidone AMNEAL [EF]	[a] Risperidone AN [EA]
						[a] Risperidone generichealth [GQ]	[a] Risperidone Sandoz [SZ]
						[a] Rispernia [ER]	[a] Rixadone [AF]

▪ RISPERIDONE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4246

Schizophrenia

Authority required (STREAMLINED)

5912

Bipolar I disorder

Clinical criteria:

The condition must be refractory to treatment, AND

The treatment must be in combination with lithium or sodium valproate, AND

The treatment must be maintenance therapy.

risperidone 25 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

8780D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*265.65	38.30	Risperdal Consta [JC]

risperidone 37.5 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

8781E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*344.65	38.30	Risperdal Consta [JC]

risperidone 50 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

8782F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*422.83	38.30	Risperdal Consta [JC]

▪ RISPERIDONE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note For item codes 8869T and 1846E, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

5903
Schizophrenia

risperidone 500 microgram tablet, 20

1846E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	5	..	*15.48	16.65	[a] APO-Risperidone [TX]	[a] Risperdal [JC]

risperidone 500 microgram tablet, 60

8869T NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	15.48	16.65	[a] Ozidal [RA]	[a] Rispa [RW]
					[a] Rispericor 0.5 [CR]	[a] Risperidone Actavis 0.5 [ED]
					[a] Risperidone AMNEAL [EF]	[a] Risperidone AN [EA]
					[a] Risperidone GH [GQ]	[a] Risperidone Sandoz [SZ]
					[a] Rispernia [ER]	[a] Rixadone [AF]

▪ RISPERIDONE

Caution In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalaties) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
5993
Behavioural disturbances
Clinical criteria:
The condition must be characterised by psychotic symptoms and aggression, AND
Patient must have dementia of the Alzheimer type, AND
Patient must have failed to respond to non-pharmacological methods of treatment, AND
The treatment must be limited to a maximum duration of 12 weeks.

Authority required (STREAMLINED)
5916
Severe behavioural disturbances
Clinical criteria:
Patient must have autism, AND
The treatment must be under the supervision of a paediatrician or psychiatrist, AND
The treatment must be in combination with non-pharmacological measures.
Population criteria:
Patient must be under 18 years of age.
Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.
The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders.

Authority required (STREAMLINED)
5898
Severe behavioural disturbances
Treatment Phase: Continuing treatment
Clinical criteria:
Patient must have autism, AND
Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, AND
The treatment must be under the supervision of a paediatrician or psychiatrist, AND
The treatment must be in combination with non-pharmacological measures.
Population criteria:
Patient must be aged 18 years or older.
Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.
The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders.

risperidone 1 mg tablet, 60

8789N NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	20.18	21.35	[a] APO-Risperidone [TX]	[a] Ozidal [RA]
					[a] Rispa [RW]	[a] Risperdal [JC]
					[a] Rispericor 1 [CR]	[a] Risperidone Actavis 1 [ED]
					[a] Risperidone AMNEAL [EF]	[a] Risperidone AN [EA]
					[a] Risperidone generichealth [GQ]	[a] Risperidone Sandoz [SZ]

						[a] Rispernia [ER]	[a] Rixadone [AF]

risperidone 1 mg/mL oral liquid, 100 mL

9293D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	2	..	111.88	38.30	Risperdal [JC]

▪ RISPERIDONE

Caution In placebo controlled trials in elderly patients with dementia there was a significantly higher incidence of cerebrovascular adverse events, such as stroke (including fatalaties) and transient ischaemic attacks, in patients treated with risperidone compared with patients treated with placebo.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note For items 8787L and 1842Y, pharmaceutical benefits that have the form tablet 0.5 mg are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

6010

Behavioural disturbances

Clinical criteria:

The condition must be characterised by psychotic symptoms and aggression, AND

Patient must have dementia of the Alzheimer type, AND

Patient must have failed to respond to non-pharmacological methods of treatment, AND

The treatment must be limited to a maximum duration of 12 weeks.

Authority required (STREAMLINED)

5911

Severe behavioural disturbances

Clinical criteria:

Patient must have autism, AND

The treatment must be under the supervision of a paediatrician or psychiatrist, AND

The treatment must be in combination with non-pharmacological measures.

Population criteria:

Patient must be under 18 years of age.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders.

Authority required (STREAMLINED)

5902

Severe behavioural disturbances

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have autism, AND

Patient must have been commenced on PBS-subsidised treatment with risperidone prior to turning 18 years of age, AND

The treatment must be under the supervision of a paediatrician or psychiatrist, AND

The treatment must be in combination with non-pharmacological measures.

Population criteria:

Patient must be aged 18 years or older.

Behaviour disturbances are defined as severe aggression and injuries to self or others where non-pharmacological methods alone have been unsuccessful.

The diagnosis of autism must be made based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or ICD-10 international classification of mental and behavioural disorders.

risperidone 500 microgram tablet, 20

1842Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	3	2	..	*15.48	16.65	[a] APO-Risperidone [TX]	[a] Risperdal [JC]

risperidone 500 microgram tablet, 60

8787L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	15.48	16.65	[a] Ozidal [RA]	[a] Rispa [RW]
						[a] Rispericor 0.5 [CR]	[a] Risperidone Actavis 0.5 [ED]
						[a] Risperidone AMNEAL [EF]	[a] Risperidone AN [EA]
						[a] Risperidone GH [GQ]	[a] Risperidone Sandoz [SZ]
						[a] Rispernia [ER]	[a] Rixadone [AF]

ANXIOLYTICS

Benzodiazepine derivatives

▪ ALPRAZOLAM

Authority required

Panic disorder

Clinical criteria:

The treatment must be for use when other treatments have failed; OR

The treatment must be for use when other treatments are inappropriate.

alprazolam 1 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2132F NP	1	2	..	17.92	19.09	[a] Alprax 1 [QA] [a] GenRx Alprazolam [GX] [a] Terry White Chemists Alprazolam [TW]	[a] Chem mart Alprazolam [CH] [a] Kalma 1 [AF]

alprazolam 2 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8118G NP	1	2	..	20.45	21.62	[a] Alprax 2 [QA] [a] GenRx Alprazolam [GX] [a] Terry White Chemists Alprazolam [TW]	[a] Chem mart Alprazolam [CH] [a] Kalma 2 [AF]

alprazolam 250 microgram tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2130D NP	1	..	..	14.96	16.13	[a] Alprax 0.25 [QA]	[a] Kalma 0.25 [AF]

alprazolam 500 microgram tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2131E NP	1	..	..	15.97	17.14	[a] Alprax 0.5 [QA]	[a] Kalma 0.5 [AF]

▪ DIAZEPAM

diazepam 10 mg/2 mL injection, 5 x 2 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5073B DP	1	..	..	16.44	17.61	Hospira Pty Limited [HH]

diazepam 2 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5071X DP	1	..	..	11.43	12.60	[a] Antenex 2 [AF] [a] Ranzepam [RA]	[a] APO-Diazepam [TX] [a] Valpam 2 [RW]

diazepam 5 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5072Y DP	1	..	..	11.53	12.70	[a] Antenex 5 [AF] [a] Ranzepam [RA]	[a] APO-Diazepam [TX] [a] Valpam 5 [RW]
			[B]2.19	13.72	12.70	[a] Valium [RO]	

▪ DIAZEPAM

Authority required

Chronic spasticity

Population criteria:

Patient must be under 18 years of age.

diazepam 1 mg/mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2669L NP	‡1	..	..	42.28	38.30	Diazepam Elixir [ON]

▪ DIAZEPAM

Note Authorities for increased maximum quantities and/or repeats for the oral forms of diazepam will be granted only for

(i) the treatment of disabling spasticity; or

(ii) malignant neoplasia (late stage); or

(iii) use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal; or

(iv) use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.

Up to six months' treatment (i.e. one month's treatment with five repeats) may be requested.

diazepam 2 mg tablet, 50

3161J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	11.43	12.60	[a] Antenex 2 [AF] [a] Ranzepam [RA]	[a] APO-Diazepam [TX] [a] Valpam 2 [RW]

diazepam 5 mg tablet, 50

3162K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	11.53	12.70	[a] Antenex 5 [AF] [a] Ranzepam [RA]	[a] APO-Diazepam [TX] [a] Valpam 5 [RW]
			[B]2.19	13.72	12.70	[a] Valium [RO]	

▪ DIAZEPAM

Note Authorities for increased maximum quantities and/or repeats for the oral forms of diazepam will be granted only for
(i) the treatment of disabling spasticity; or
(ii) malignant neoplasia (late stage); or
(iii) use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal; or
(iv) use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past six months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal.

Note Up to six months' treatment (i.e. one month's treatment with five repeats) may be requested.

diazepam 10 mg/2 mL injection, 5 x 2 mL ampoules

2558P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	16.44	17.61	Hospira Pty Limited [HH]

▪ OXAZEPAM

oxazepam 15 mg tablet, 25

5192G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	11.84	13.01	[a] Alepam 15 [AF]
			[B]2.66	14.50	13.01	[a] Serepax [QA]

oxazepam 30 mg tablet, 25

5193H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	11.50	12.67	[a] Alepam 30 [AF] [a] Murelax [RW]	[a] APO-Oxazepam [TX]
			[B]2.33	13.83	12.67	[a] Serepax [QA]	

▪ OXAZEPAM

Note Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of oxazepam below.

oxazepam 15 mg tablet, 25

3132W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	11.84	13.01	[a] Alepam 15 [AF]
			[B]2.66	14.50	13.01	[a] Serepax [QA]

oxazepam 30 mg tablet, 25

3133X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	11.50	12.67	[a] Alepam 30 [AF] [a] Murelax [RW]	[a] APO-Oxazepam [TX]
			[B]2.33	13.83	12.67	[a] Serepax [QA]	

▪ OXAZEPAM

Authority required

Malignant neoplasia (late stage)

Authority required

For use by patients who are receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities and who have been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

Authority required

For use by a patient who is receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult and who has been demonstrated, within the past 6 months, to be benzodiazepine dependent by an unsuccessful attempt at gradual withdrawal

oxazepam 15 mg tablet, 25

3134Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*13.27	14.44	[a] Alepam 15 [AF]
			[B]5.32	*18.59	14.44	[a] Serepax [QA]

oxazepam 30 mg tablet, 25

3135B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*12.59	13.76	[a] Alepam 30 [AF] [a] Murelax [RW]	[a] APO-Oxazepam [TX]
			[B]4.66	*17.25	13.76	[a] Serepax [QA]	

HYPNOTICS AND SEDATIVES

Benzodiazepine derivatives

▪ NITRAZEPAM

nitrazepam 5 mg tablet, 25

5189D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	12.03	13.20	[a] Alodorm [AF]
			[B]1.24	13.27	13.20	[a] Mogadon [IA]

▪ NITRAZEPAM

Note Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of nitrazepam below.

nitrazepam 5 mg tablet, 25

2723H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	12.03	13.20	[a] Alodorm [AF]
			[B]1.24	13.27	13.20	[a] Mogadon [IA]

▪ NITRAZEPAM

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required
Myoclonic epilepsy
Authority required
Malignant neoplasia (late stage)
Authority required
Insomnia
Clinical criteria:
Patient must be receiving this drug for the management of insomnia, AND
Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, AND
Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.
Authority required
Insomnia
Clinical criteria:
Patient must be receiving this drug for the management of insomnia, AND
Patient must be receiving long-term nursing care, AND
Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, AND
Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

nitrazepam 5 mg tablet, 25

2732T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*13.65	14.82	[a] Alodorm [AF]
			[B]2.48	*16.13	14.82	[a] Mogadon [IA]

▪ TEMAZEPAM

temazepam 10 mg tablet, 25

5221T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	11.23	12.40	[a] APO-Temazepam [TX] [a] Temtabs [FM]	[a] Temaze [AF]
			[B]3.48	14.71	12.40	[a] Normison [QA]	

▪ TEMAZEPAM

Note Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of temazepam.

temazepam 10 mg tablet, 25

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2089Y NP	1	..	..	11.23	12.40	[a] APO-Temazepam [TX] [a] Temtabs [FM]	[a] Temaze [AF]
			[B]3.48	14.71	12.40	[a] Normison [QA]	

▪ TEMAZEPAM

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Malignant neoplasia (late stage)

Authority required

Insomnia

Clinical criteria:

Patient must be receiving this drug for the management of insomnia, AND

Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility, AND

Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

Authority required

Insomnia

Clinical criteria:

Patient must be receiving this drug for the management of insomnia, AND

Patient must be receiving long-term nursing care, AND

Patient must be one in respect of whom a Carer Allowance is payable as a disabled adult, AND

Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

temazepam 10 mg tablet, 25

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2088X NP	2	5	..	*12.05	13.22	[a] APO-Temazepam [TX] [a] Temtabs [FM]	[a] Temaze [AF]
			[B]6.96	*19.01	13.22	[a] Normison [QA]	

▪ PSYCHOANALEPTICS

ANTIDEPRESSANTS

Non-selective monoamine reuptake inhibitors

▪ AMITRIPTYLINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

amitriptyline hydrochloride 10 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2417F NP	1	2	..	12.93	14.10	[a] Amitriptyline Alphapharm 10 [AL] [a] Chem mart Amitriptyline [CH]	[a] APO-Amitriptyline 10 [TX] [a] Terry White Chemists Amitriptyline [TW]
			[B]1.95	14.88	14.10	[a] Endep 10 [AF]	

amitriptyline hydrochloride 25 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2418G NP	1	2	..	13.12	14.29	[a] Amitriptyline Alphapharm 25 [AL] [a] Chem mart Amitriptyline [CH]	[a] APO-Amitriptyline 25 [TX] [a] Terry White Chemists Amitriptyline [TW]
			[B]1.96	15.08	14.29	[a] Endep 25 [AF]	

amitriptyline hydrochloride 50 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2429W NP	1	2	..	13.52	14.69	[a] Amitriptyline Alphapharm 50 [AL]	[a] APO-Amitriptyline 50 [TX]
						[a] Chem mart Amitriptyline [CH]	[a] Terry White Chemists Amitriptyline [TW]
			[B]1.95	15.47	14.69	[a] Endep 50 [AF]	

▪ CLOMIPRAMINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Cataplexy associated with narcolepsy

Restricted benefit
Obsessive-compulsive disorder

Restricted benefit
Phobic disorders in adults

clomipramine hydrochloride 25 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1561E NP	1	2	..	17.14	18.31	[a] Chem mart Clomipramine [CH]	[a] GenRx Clomipramine [GX]
						[a] Placil [AF]	[a] Terry White Chemists Clomipramine [TW]
			[B]2.74	19.88	18.31	[a] Anafranil 25 [NV]	

▪ DOTHIEPIN

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

dothiepin hydrochloride 25 mg capsule, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1357K NP	1	2	..	12.99	14.16	Dothep 25 [AF]

dothiepin hydrochloride 75 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1358L NP	1	2	..	12.99	14.16	Dothep 75 [AF]

▪ DOXEPIN

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

doxepin 10 mg capsule, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1011F NP	1	2	..	13.31	14.48	Deptran 10 [AF]
			[B]5.57	18.88	14.48	Sinequan [PF]

doxepin 25 mg capsule, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1013H NP	1	2	..	13.42	14.59	Deptran 25 [AF]
			[B]5.45	18.87	14.59	Sinequan [PF]

doxepin 50 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1012G NP	1	2	..	14.22	15.39	Deptran 50 [AF]

▪ IMIPRAMINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

imipramine hydrochloride 10 mg tablet, 50

2420J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	12.26	13.43	[a] Tolerade 10 [PQ]
			[B]2.43	14.69	13.43	[a] Tofranil 10 [ZC]

imipramine hydrochloride 25 mg tablet, 50

2421K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	15.65	16.82	[a] Tolerade 25 [PQ]
			[B]2.41	18.06	16.82	[a] Tofranil 25 [ZC]

▪ NORTRIPTYLINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Major depression where other antidepressant therapy has failed

Restricted benefit
Major depression where other antidepressant therapy is contraindicated

nortriptyline 10 mg tablet, 50

2522R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	16.12	17.29	Allegron [RW]

nortriptyline 25 mg tablet, 50

2523T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	17.59	18.76	Allegron [RW]

Selective serotonin reuptake inhibitors

▪ CITALOPRAM

Restricted benefit
Major depressive disorders

citalopram 10 mg tablet, 28

8702B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	11.56	12.73	[a] Celapram [AF] [a] Citalopram AN [EF] [a] Talam [RW]	[a] Citalopram Actavis [EA] [a] Citalopram-GA [ED]

citalopram 20 mg tablet, 28

8220P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.14	13.31	[a] APO-Citalopram [TX] [a] Celapram [AF] [a] Chem mart Citalopram [CH] [a] Citalopram Actavis [ED] [a] Citalopram-GA [EF] [a] Citalopram Sandoz [SZ] [a] Talam [RW]	[a] Auro-Citalopram 20 [DO] [a] Celica [RA] [a] Ciazil [UA] [a] Citalopram AN [EA] [a] Citalopram generichealth [GQ] [a] Pharmacor Citalo 20 [CR] [a] Terry White Chemists Citalopram [TW]
			[B]6.24	18.38	13.31	[a] Cipramil [LU]	

citalopram 40 mg tablet, 28

8703C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.33	14.50	[a] APO-Citalopram [TX] [a] Celapram [AF] [a] Citalopram AN [EA] [a] Citalopram Sandoz [SZ]	[a] Auro-Citalopram 40 [DO] [a] Citalopram Actavis [ED] [a] Citalopram-GA [EF] [a] Talam [RW]

▪ ESCITALOPRAM

Restricted benefit
Major depressive disorders

escitalopram 10 mg tablet, 28

8700X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.36	14.53	[a] APO-Escitalopram [TX] [a] Cilopam-S [ER] [a] Escitalopram AN [EA]	[a] Chem mart Escitalopram [CH] [a] Escicor 10 [RA] [a] Escitalopram-DRLA [RZ]

					[a] Escitalopram GA [ED]	[a] Escitalopram generichealth [GQ]
					[a] Esipram [CF]	[a] Esitalo [SZ]
					[a] Lexam 10 [RW]	[a] LoxaLate [AF]
					[a] Pharmacor Escitalopram 10 [CR]	[a] Terry White Chemists Escitalopram [TW]
		[B]7.04	20.40	14.53	[a] Lexapro [LU]	

escitalopram 20 mg tablet, 28

8701Y NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	13.38	14.55	[a] APO-Escitalopram [TX]	[a] Chem mart Escitalopram [CH]
					[a] Cilopam-S [ER]	[a] Escicor 20 [RA]
					[a] Escitalopram AN [EA]	[a] Escitalopram-DRLA [RZ]
					[a] Escitalopram GA [ED]	[a] Escitalopram generichealth [GQ]
					[a] Esipram [CF]	[a] Esitalo [SZ]
					[a] Lexam 20 [RW]	[a] LoxaLate [AF]
					[a] Pharmacor Escitalopram 20 [CR]	[a] Terry White Chemists Escitalopram [TW]
		[B]7.38	20.76	14.55	[a] Lexapro [LU]	

▪ ESCITALOPRAM

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD)

Clinical criteria:

The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, AND

Patient must not have responded to non-pharmacological therapy, AND

Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD)

Clinical criteria:

The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, AND

Patient must not have responded to non-pharmacological therapy, AND

Patient must have been assessed by a psychiatrist.

Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD)

Clinical criteria:

The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, AND

Patient must not have responded to non-pharmacological therapy, AND

Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD)

Clinical criteria:

The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, AND

Patient must not have responded to non-pharmacological therapy, AND

Patient must have been assessed by a psychiatrist.

escitalopram 10 mg tablet, 28

9432K NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	13.36	14.53	[a] Esipram [CF]
		[B]7.04	20.40	14.53	[a] Lexapro [LU]

escitalopram 20 mg tablet, 28

9433L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	13.38	14.55	[a] Esipram [CF]
		[B]7.38	20.76	14.55	[a] Lexapro [LU]

▪ ESCITALOPRAM

Restricted benefit

Major depressive disorders

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD)

Clinical criteria:

The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, AND

Patient must not have responded to non-pharmacological therapy, AND

Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD)

Clinical criteria:

The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, AND

Patient must not have responded to non-pharmacological therapy, AND

Patient must have been assessed by a psychiatrist.

Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD)

Clinical criteria:

The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, AND

Patient must not have responded to non-pharmacological therapy, AND

Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD)

Clinical criteria:

The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, AND

Patient must not have responded to non-pharmacological therapy, AND

Patient must have been assessed by a psychiatrist.

escitalopram 20 mg/mL oral liquid, 15 mL

10181W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	36.39	37.56	Lexapro [LU]

▪ FLUOXETINE

Restricted benefit

Major depressive disorders

Restricted benefit

Obsessive-compulsive disorder

fluoxetine 20 mg capsule, 28

1434L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.70	15.87	[a] Auscap Aspen [RW] [a] Fluoxetine 20 [CR] [a] Fluoxetine-GA [ED] [a] Fluoxetine RBX [RA] [a] GenRx Fluoxetine [GX] [a] Terry White Chemists Fluoxetine [TW]	[a] Chem mart Fluoxetine [CH] [a] Fluoxetine AN [EA] [a] Fluoxetine generichealth [GQ] [a] Fluoxetine Sandoz [SZ] [a] Lovan [AL] [a] Zactin [AF]
			[B]1.36	16.06	15.87	[a] Prozac 20 [LY]	

fluoxetine 20 mg tablet: dispersible, 28

8270G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.70	15.87	[a] Lovan 20 Tab [AL]	[a] Zactin Tablet [AF]
			[B]1.36	16.06	15.87	[a] Prozac Tab [LY]	

▪ FLUVOXAMINE

Restricted benefit

Major depressive disorders

Restricted benefit

Obsessive-compulsive disorder

fluvoxamine maleate 100 mg tablet, 30

8174F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.15	21.32	[a] APO-Fluvoxamine [TX] [a] Fluvoxamine GA [EA] [a] Voxam [SZ]	[a] Faverin 100 [RW] [a] Movox 100 [AF]
			[B]3.49	23.64	21.32	[a] Luvox [GO]	

fluvoxamine maleate 50 mg tablet, 30

8512B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.84	18.01	[a] APO-Fluvoxamine [TX] [a] Fluvoxamine GA [EA] [a] Voxam [SZ]	[a] Faverin 50 [RW] [a] Movox 50 [AL]
			[B]3.50	20.34	18.01	[a] Luvox [GO]	

▪ PAROXETINE

Note Pharmaceutical benefits that have the form paroxetine tablet 20 mg (as hydrochloride) and pharmaceutical benefits that have the form paroxetine tablet 20 mg (as mesilate) are equivalent for the purposes of substitution.

Restricted benefit
Major depressive disorders
Restricted benefit
Obsessive-compulsive disorder
Restricted benefit
Panic disorder

paroxetine 20 mg tablet, 30

2242B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.36	16.53	[a] Chem mart Paroxetine [CH] [a] GenRx Paroxetine [GX] [a] Paroxetine AN [EA] [a] Paroxetine GH [GQ] [a] Paxtine [AF] [a] Terry White Chemists Paroxetine [TW]	[a] Extine 20 [RW] [a] Paroxetine Actavis [ED] [a] Paroxetine-GA [FM] [a] Paroxetine Sandoz [SZ] [a] Roxet 20 [DO]
			[B]2.19	17.55	16.53	[a] Aropax [AS]	

paroxetine 20 mg tablet, 30

9197C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	15.36	16.53	[a] Paroxetine generichealth [GQ]

▪ SERTRALINE

Restricted benefit
Major depressive disorders

sertraline 100 mg tablet, 30

2237R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.42	13.59	[a] APO-Sertraline [TX] [a] Chem mart Sertraline [CH] [a] GenRx Sertraline [GX] [a] Sertracor 100 [CR] [a] Sertraline AN [EA] [a] Sertraline Sandoz [SZ] [a] Terry White Chemists Sertraline [TW]	[a] Auro-Sertraline 100 [DO] [a] Eleva 100 [AF] [a] Sertra 100 [RW] [a] Sertraline Actavis [ED] [a] Sertraline generichealth [GQ] [a] Setrona [RA] [a] Xydep 100 [EF]
			[B]5.28	17.70	13.59	[a] Zoloft [PF]	

sertraline 50 mg tablet, 30

2236Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.42	13.59	[a] APO-Sertraline [TX] [a] Chem mart Sertraline [CH] [a] GenRx Sertraline [GX] [a] Sertracor 50 [CR] [a] Sertraline AN [EA] [a] Sertraline Sandoz [SZ] [a] Terry White Chemists Sertraline [TW]	[a] Auro-Sertraline 50 [DO] [a] Eleva 50 [AF] [a] Sertra 50 [RW] [a] Sertraline Actavis [ED] [a] Sertraline generichealth [GQ] [a] Setrona [RA] [a] Xydep 50 [EF]
			[B]5.28	17.70	13.59	[a] Zoloft [PF]	

▪ SERTRALINE

Restricted benefit
Obsessive-compulsive disorder
Restricted benefit
Panic disorder where other treatments have failed or are inappropriate

sertraline 100 mg tablet, 30

8837D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.42	13.59	[a] Auro-Sertraline 100 [DO] [a] Sertraline Actavis [ED] [a] Xydep 100 [EF]	[a] Eleva 100 [AF] [a] Sertraline AN [EA]
			[B]5.28	17.70	13.59	[a] Zoloft [PF]	

sertraline 50 mg tablet, 30

8836C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	12.42	13.59	[a] Auro-Sertraline 50 [DO]	[a] Eleva 50 [AF]

					[a] Sertraline Actavis [ED]	[a] Sertraline AN [EA]
					[a] Xydep 50 [EF]	
		[B]5.28	17.70	13.59	[a] Zoloft [PF]	

Monoamine oxidase inhibitors, non-selective

▪ PHENELZINE

Caution This drug is an irreversible monoamine oxidase inhibitor.

Restricted benefit

Depression where all other anti-depressant therapy has failed or is inappropriate

phenelzine 15 mg tablet, 100

2856H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	91.32	38.30	Nardil [LM]

▪ TRANYLCYPROMINE

Caution This drug is an irreversible monoamine oxidase inhibitor.

tranylcypromine 10 mg tablet, 50

2444P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	55.25	38.30	Parnate [GH]

Monoamine oxidase A inhibitors

▪ MOCLOBEMIDE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Major depressive disorders

moclobemide 150 mg tablet, 60

1900B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.97	17.14	[a] Amira 150 [AF]	[a] Clobemix [ED]
						[a] GenRx Moclobemide [GX]	[a] Moclobemide AN [EA]
						[a] Moclobemide Sandoz [SZ]	[a] Mohexal [HX]
			[B]0.32	16.29	17.14	[a] Aurorix [HM]	

moclobemide 300 mg tablet, 60

8003F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.10	22.27	[a] Amira 300 [AF]	[a] Clobemix [ED]
						[a] GenRx Moclobemide [GX]	[a] Moclobemide AN [EA]
						[a] Moclobemide Sandoz [SZ]	
			[B]0.64	21.74	22.27	[a] Aurorix 300 mg [HM]	

Other antidepressants

▪ DESVENLAFAXINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 50 mg, desvenlafaxine tablet (modified release) 50 mg (as benzoate) and desvenlafaxine tablet (extended release) 50 mg (as succinate) are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 100 mg, desvenlafaxine tablet (modified release) 100 mg (as benzoate) and desvenlafaxine tablet (extended release) 100 mg (as succinate) are equivalent for the purposes of substitution.

Restricted benefit

Major depressive disorders

desvenlafaxine 100 mg tablet: modified release, 28

10231L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	34.77	35.94	[a] Desfax [AF]	[a] Desvenlafaxine Actavis [EA]

desvenlafaxine 100 mg tablet: modified release, 28

10245F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	34.77	35.94	[a] APO-Desvenlafaxine MR [TX]	[a] Desvenlafaxine GH XR [GQ]

desvenlafaxine 100 mg tablet: modified release, 28

9367B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	34.77	35.94	[a] Pristiq [PF]

desvenlafaxine 50 mg tablet: modified release, 28

10234P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	30.26	31.43	[a] APO-Desvenlafaxine MR [TX]	[a] Desvenlafaxine GH XR [GQ]

desvenlafaxine 50 mg tablet: modified release, 28

10241B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	30.26	31.43	[a] Desfax [AF]	[a] Desvenlafaxine Actavis [EA]

desvenlafaxine 50 mg tablet: modified release, 28

9366Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	30.26	31.43	[a] Pristiq [PF]

▪ DULOXETINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit
Major depressive disorders

duloxetine 30 mg capsule: enteric, 28

9155W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	16.96	18.13	[a] Andepra [EL] [a] Chem mart Duloxetine [CH] [a] Deotine 30 [SZ] [a] Drulox [ED] [a] Duloxetine GH [GQ] [a] Duloxetine Sandoz [HX] [a] Terry White Chemists Duloxetine [TW]	[a] APO-Duloxetine [TX] [a] Coperin [AF] [a] Depreta 30 [DO] [a] Duloxetine AN [EA] [a] Duloxetine RBX [RA] [a] Pharmacor Duloxetine 30 [CR]
			[B]3.00	19.96	18.13	[a] Cymbalta [LY]	

duloxetine 60 mg capsule: enteric, 28

9156X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.74	20.91	[a] Andepra [EL] [a] Chem mart Duloxetine [CH] [a] Deotine 60 [SZ] [a] Drulox [ED] [a] Duloxetine GH [GQ] [a] Duloxetine Sandoz [HX] [a] Terry White Chemists Duloxetine [TW]	[a] APO-Duloxetine [TX] [a] Coperin [AF] [a] Depreta 60 [DO] [a] Duloxetine AN [EA] [a] Duloxetine RBX [RA] [a] Pharmacor Duloxetine 60 [CR]
			[B]3.00	22.74	20.91	[a] Cymbalta [LY]	

▪ LITHIUM CARBONATE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

lithium carbonate 250 mg tablet, 200

3059B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	19.06	20.23	Lithicarb [AS]

lithium carbonate 450 mg tablet: modified release, 100

8290H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	2	..	*33.47	34.64	Quilonum SR [AS]

▪ MIANSERIN

Caution Neutropenia and agranulocytosis are more frequent in the elderly, especially in the early months of therapy.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Severe depression

mianserin hydrochloride 10 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1627P NP	1	5	..	18.22	19.39	Lumin 10 [AF]

mianserin hydrochloride 20 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1628Q NP	1	5	..	26.87	28.04	Lumin 20 [AF]

▪ MIRTAZAPINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Major depressive disorders

MIRTAZAPINE Tablet 15 mg (orally disintegrating), 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8855C NP	1	5	..	15.28	16.45	[a] Milivin OD 15 [DO] [a] Mirtazapine Sandoz ODT 15 [SZ]	[a] Mirtazapine AN ODT [EA] [a] Remeron SolTab [AF]
			[B]1.20	16.48	16.45	[a] Avanza SolTab [MK]	

MIRTAZAPINE Tablet 30 mg (orally disintegrating), 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8856D NP	1	5	..	16.89	18.06	[a] Milivin OD 30 [DO] [a] Mirtazapine Sandoz ODT 30 [SZ]	[a] Mirtazapine AN ODT [EA] [a] Remeron SolTab [AF]
			[B]1.20	18.09	18.06	[a] Avanza SolTab [MK]	

MIRTAZAPINE Tablet 45 mg (orally disintegrating), 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8857E NP	1	5	..	20.17	21.34	[a] Milivin OD 45 [DO] [a] Mirtazapine Sandoz ODT 45 [SZ]	[a] Mirtazapine AN ODT [EA] [a] Remeron SolTab [AF]
			[B]1.20	21.37	21.34	[a] Avanza SolTab [MK]	

mirtazapine 15 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
9365X NP	1	5	..	13.24	14.41	[a] APO-Mirtazapine [TX] [a] Mirtazapine AN [EA]	[a] Axit 15 [AF]

mirtazapine 30 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8513C NP	1	5	..	14.65	15.82	[a] APO-Mirtazapine [TX] [a] Axit 30 [AF] [a] GenRx Mirtazapine [GX] [a] Mirtazapine-GA [ED] [a] Mirtazapine Sandoz [SZ] [a] Terry White Chemists Mirtazapine [TW]	[a] Aurozapine 30 [DO] [a] Chem mart Mirtazapine [CH] [a] Mirtazapine AN [EA] [a] Mirtazapine GH [GQ] [a] Mirtazon [RW]
			[B]3.50	18.15	15.82	[a] Avanza [MK]	

mirtazapine 45 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8883M NP	1	5	..	17.46	18.63	[a] APO-Mirtazapine [TX] [a] Axit 45 [AF] [a] Mirtazapine AN [EA] [a] Mirtazapine GH [GQ] [a] Mirtazon [RW]	[a] Aurozapine 45 [DO] [a] Chem mart Mirtazapine [CH] [a] Mirtazapine-GA [ED] [a] Mirtazapine Sandoz [SZ] [a] Terry White Chemists Mirtazapine [TW]
			[B]3.50	20.96	18.63	[a] Avanza [MK]	

▪ REBOXETINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Major depressive disorders

reboxetine 4 mg tablet, 60

8583R (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	37.13	38.30	Edronax [PF]

▪ VENLAFAXINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Major depressive disorders

venlafaxine 150 mg capsule: modified release, 28

8302Y (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	17.56	18.73	[a] Altven [FZ]	[a] APO-Venlafaxine XR [TX]
					[a] Blooms the Chemist Venlafaxine XR [IB]	[a] Chem mart Venlafaxine XR [CH]
					[a] Efexor-XR [PF]	[a] Elaxine SR 150 [ZP]
					[a] Enlafax-XR [AF]	[a] Terry White Chemists Venlafaxine XR [TW]
					[a] Venlafaxine Actavis XR [ED]	[a] Venlafaxine AN SR [EA]
					[a] Venlafaxine generichealth XR [GQ]	[a] Venlafaxine Sandoz XR [SZ]
					[a] Venlafaxine SR SCP 150 [CR]	[a] Venla RBX [RA]

venlafaxine 37.5 mg capsule: modified release, 28

8868R (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	13.74	14.91	[a] Altven [FZ]	[a] Efexor-XR [PF]
					[a] Elaxine SR 37.5 [ZP]	[a] Venlafaxine Actavis XR [ED]
					[a] Venlafaxine AN SR [EA]	

venlafaxine 75 mg capsule: modified release, 28

8301X (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.28	17.45	[a] Altven [FZ]	[a] APO-Venlafaxine XR [TX]
					[a] Blooms the Chemist Venlafaxine XR [IB]	[a] Chem mart Venlafaxine XR [CH]
					[a] Efexor-XR [PF]	[a] Elaxine SR 75 [ZP]
					[a] Enlafax-XR [AF]	[a] Terry White Chemists Venlafaxine XR [TW]
					[a] Venlafaxine Actavis XR [ED]	[a] Venlafaxine AN SR [EA]
					[a] Venlafaxine generichealth XR [GQ]	[a] Venlafaxine Sandoz XR [SZ]
					[a] Venlafaxine SR SCP 75 [CR]	[a] Venla RBX [RA]

PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS

Centrally acting sympathomimetics

▪ ATOMOXETINE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4591

Attention deficit hyperactivity disorder

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be or have been diagnosed by a paediatrician or psychiatrist according to the DSM-5 criteria, AND

Patient must have a contraindication to dexamphetamine or methylphenidate as specified in TGA-approved product information; OR

Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamphetamine or methylphenidate treatment and is of a severity necessitating treatment withdrawal; OR

Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR

Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamphetamine and treatment with methylphenidate (not simultaneously).

Population criteria:

Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

Authority required (STREAMLINED)

4578

Attention deficit hyperactivity disorder

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug.

atomoxetine 10 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9092M	2	5	..	*197.61	38.30	Strattera [LY]

atomoxetine 100 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9290Y	1	5	..	131.92	38.30	Strattera [LY]

atomoxetine 18 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9093N	2	5	..	*197.61	38.30	Strattera [LY]

atomoxetine 25 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9094P	2	5	..	*197.61	38.30	Strattera [LY]

atomoxetine 40 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9095Q	2	5	..	*197.61	38.30	Strattera [LY]

atomoxetine 60 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9096R	2	5	..	*197.61	38.30	Strattera [LY]

atomoxetine 80 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9289X	1	5	..	131.92	38.30	Strattera [LY]

▪ DEXAMPHETAMINE

Note Care must be taken to comply with the provisions of State/Territory law when prescribing dexamphetamine.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Use in attention deficit hyperactivity disorder, in accordance with State/Territory law

Authority required

Narcolepsy

dexamphetamine sulfate 5 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1165H (NP)	1	5	..	20.81	21.98	Aspen Pharma Pty Ltd [QA]

▪ LISDEXAMFETAMINE

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Attention deficit hyperactivity disorder
Clinical criteria:
Patient must require continuous coverage over 12 hours.
Population criteria:
Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

lisdexamfetamine dimesilate 30 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10486X NP	1	5	..	116.33	38.30	Vyvanse [ZI]

lisdexamfetamine dimesilate 50 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10474G NP	1	5	..	116.33	38.30	Vyvanse [ZI]

lisdexamfetamine dimesilate 70 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10492F NP	1	5	..	116.33	38.30	Vyvanse [ZI]

▪ METHYLPHENIDATE

Note Care must be taken to comply with the provisions of State/Territory law when prescribing methylphenidate hydrochloride.
Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Treatment of attention deficit hyperactivity disorder (ADHD) in a patient diagnosed between the ages of 6 and 18 years inclusive, who has demonstrated a response to immediate release methylphenidate hydrochloride with no emergence of serious adverse events, and who requires continuous coverage over 12 hours

methylphenidate hydrochloride 18 mg tablet: modified release, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2387P NP	1	5	..	51.02	38.30	Concerta [JC]

methylphenidate hydrochloride 27 mg tablet: modified release, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2172H NP	1	5	..	55.16	38.30	Concerta [JC]

methylphenidate hydrochloride 36 mg tablet: modified release, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2388Q NP	1	5	..	59.29	38.30	Concerta [JC]

methylphenidate hydrochloride 54 mg tablet: modified release, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2432B NP	1	5	..	68.44	38.30	Concerta [JC]

▪ METHYLPHENIDATE

Note Care must be taken to comply with the provisions of State/Territory law when prescribing methylphenidate hydrochloride.
Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Treatment of attention deficit hyperactivity disorder (ADHD) in a patient diagnosed between the ages of 6 and 18 years inclusive, who has demonstrated a response to immediate release methylphenidate hydrochloride with no emergence of serious adverse events, and who requires continuous coverage over 8 hours

methylphenidate hydrochloride 10 mg capsule: modified release, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3440C NP	1	5	..	35.00	36.17	Ritalin LA [NV]

methylphenidate hydrochloride 20 mg capsule: modified release, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2276T NP	1	5	..	44.27	38.30	Ritalin LA [NV]

methylphenidate hydrochloride 30 mg capsule: modified release, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2280B NP	1	5	..	51.73	38.30	Ritalin LA [NV]

methylphenidate hydrochloride 40 mg capsule: modified release, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2283E NP	1	5	..	54.26	38.30	Ritalin LA [NV]

▪ METHYLPHENIDATE

Note Care must be taken to comply with the provisions of State/Territory law when prescribing methylphenidate hydrochloride.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Use in attention deficit hyperactivity disorder, in accordance with State/Territory law

methylphenidate hydrochloride 10 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8839F NP	1	5	..	20.86	22.03	Ritalin 10 [NV]

▪ MODAFINIL

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note This drug is not PBS-subsidised when used in combination with PBS-subsidised dexamphetamine sulfate.

Authority required

Narcolepsy

Treatment Phase: Initial treatment

Clinical criteria:

The treatment must be for use when therapy with dexamphetamine sulfate poses an unacceptable medical risk; OR

The treatment must be for use when intolerance to dexamphetamine sulfate is of a severity to necessitate treatment withdrawal, AND

Patient must have experienced excessive daytime sleepiness, recurrent naps or lapses into sleep occurring almost daily for at least 3 months, AND

Patient must have a definite history of cataplexy; OR

Patient must have a mean sleep latency less than or equal to 10 minutes on a Multiple Sleep Latency Test (MSLT); OR

Patient must have an electroencephalographic (EEG) recording showing the pathologically rapid development of REM sleep, AND

Patient must not have any medical or psychiatric disorder that could otherwise account for the hypersomnia.

Treatment criteria:

Must be treated by a qualified sleep medicine practitioner or neurologist.

The presence of any one of the following indicates treatment with dexamphetamine sulfate poses an unacceptable medical risk:

(a) a psychiatric disorder;

(b) a cardiovascular disorder;

(c) a history of substance abuse;

(d) glaucoma;

(e) any other absolute contraindication to dexamphetamine sulfate as specified in the TGA-approved Product Information.

The MSLT must be preceded by nocturnal polysomnography. Sleep prior to the MSLT must be at least 6 hours in duration.

The authority application must be made in writing and must include the following:

(a) a completed authority prescription form; and

(b) a completed Narcolepsy Initial PBS authority application and Supporting information form; and

(c) details of the contraindication or intolerance to dexamphetamine sulfate; and

(d) either:

(i) the result and date of the polysomnography test and Multiple Sleep Latency Test (MSLT) conducted by, or under the supervision of, a qualified sleep medicine practitioner; or

(ii) the result and date of the electroencephalograph (EEG), conducted by, or under the supervision of, a neurologist.

The polysomnography, MSLT or EEG test reports must be provided with the authority application.

Authority required

Narcolepsy
Treatment Phase: Continuing treatment
Clinical criteria:
Patient must have previously been issued with an authority prescription for this drug.

modafinil 100 mg tablet, 60

8816B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*284.57	38.30	[a] Modafin [RW]	[a] Modavigil [TB]

ANTI-DEMENTIA DRUGS

Anticholinesterases

▪ DONEPEZIL

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
4219
Mild to moderately severe Alzheimer disease
Treatment Phase: Continuing
Clinical criteria:
Patient must have received six months of sole PBS-subsidised initial therapy with this drug, AND
Patient must demonstrate a clinically meaningful response to the initial treatment, AND
The treatment must be the sole PBS-subsidised therapy for this condition.
Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.
Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.
Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.
Clinically meaningful response to treatment is demonstrated in the following areas:
Patient's quality of life including but not limited to level of independence and happiness;
Patient's cognitive function including but not limited to memory, recognition and interest in environment;
Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

donepezil hydrochloride 10 mg tablet, 28

2479L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	29.33	30.50	[a] APO-Donepezil [TX] [a] Aricept [PF] [a] Aridon APN 10 [RF] [a] Donepezil AN [EA] [a] Donepezil-GA [ED] [a] Donepezil RBX [RA] [a] Pharmacor Donepezil 10 [CR]	[a] Arazil [AF] [a] Aridon 10 [RW] [a] Chem mart Donepezil [CH] [a] Donepezil-DRLA [RZ] [a] Donepezil generichealth [GQ] [a] Donepezil Sandoz [SZ] [a] Terry White Chemists Donepezil [TW]

donepezil hydrochloride 5 mg tablet, 28

2532G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	29.33	30.50	[a] APO-Donepezil [TX] [a] Aricept [PF] [a] Aridon APN 5 [RF] [a] Donepezil AN [EA] [a] Donepezil-GA [ED] [a] Donepezil RBX [RA] [a] Pharmacor Donepezil 5 [CR]	[a] Arazil [AF] [a] Aridon 5 [RW] [a] Chem mart Donepezil [CH] [a] Donepezil-DRLA [RZ] [a] Donepezil generichealth [GQ] [a] Donepezil Sandoz [SZ] [a] Terry White Chemists Donepezil [TW]

▪ DONEPEZIL

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required
Mild to moderately severe Alzheimer disease
Treatment Phase: Initial
Clinical criteria:

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, AND

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), AND

The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, AND

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), AND

The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;

(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;

(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;

(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;

(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;

(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

donepezil hydrochloride 10 mg tablet, 28

8496E NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	29.33	30.50	[a] APO-Donepezil [TX]	[a] Arazil [AF]
					[a] Aricept [PF]	[a] Aridon 10 [RW]
					[a] Aridon APN 10 [RF]	[a] Chem mart Donepezil [CH]
					[a] Donepezil AN [EA]	[a] Donepezil-DRLA [RZ]
					[a] Donepezil-GA [ED]	[a] Donepezil generichealth [GQ]
					[a] Donepezil RBX [RA]	[a] Donepezil Sandoz [SZ]
					[a] Pharmacor Donepezil 10 [CR]	[a] Terry White Chemists Donepezil [TW]

donepezil hydrochloride 5 mg tablet, 28

8495D NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	29.33	30.50	[a] APO-Donepezil [TX]	[a] Arazil [AF]
					[a] Aricept [PF]	[a] Aridon 5 [RW]
					[a] Aridon APN 5 [RF]	[a] Chem mart Donepezil [CH]
					[a] Donepezil AN [EA]	[a] Donepezil-DRLA [RZ]
					[a] Donepezil-GA [ED]	[a] Donepezil generichealth [GQ]
					[a] Donepezil RBX [RA]	[a] Donepezil Sandoz [SZ]
					[a] Pharmacor Donepezil 5 [CR]	[a] Terry White Chemists Donepezil [TW]

▪ GALANTAMINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4219

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

Clinical criteria:

Patient must have received six months of sole PBS-subsidised initial therapy with this drug, AND

Patient must demonstrate a clinically meaningful response to the initial treatment, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

galantamine 16 mg capsule: modified release, 28

2537M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	44.92	38.30	[a] APO-Galantamine MR [TX] [a] Galantyl [AF] [a] Reminyl [JC]	[a] Galantamine AN SR [EA] [a] Gamine XR [RW]

galantamine 24 mg capsule: modified release, 28

2531F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	51.54	38.30	[a] APO-Galantamine MR [TX] [a] Galantyl [AF] [a] Reminyl [JC]	[a] Galantamine AN SR [EA] [a] Gamine XR [RW]

galantamine 8 mg capsule: modified release, 28

2463P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	38.63	38.30	[a] APO-Galantamine MR [TX] [a] Galantyl [AF] [a] Reminyl [JC]	[a] Galantamine AN SR [EA] [a] Gamine XR [RW]

▪ GALANTAMINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, AND

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), AND

The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, AND

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), AND

The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;

(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;

(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;

(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;

(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;

(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

galantamine 16 mg capsule: modified release, 28

8771P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	44.92	38.30	[a] APO-Galantamine MR [TX] [a] Galantyl [AF] [a] Reminyl [JC]	[a] Galantamine AN SR [EA] [a] Gamine XR [RW]

galantamine 24 mg capsule: modified release, 28

8772Q NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	51.54	38.30	[a] APO-Galantamine MR [TX] [a] Galantyl [AF] [a] Reminyl [JC]	[a] Galantamine AN SR [EA] [a] Gamine XR [RW]

galantamine 8 mg capsule: modified release, 28

8770N NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	38.63	38.30	[a] APO-Galantamine MR [TX] [a] Galantyl [AF] [a] Reminyl [JC]	[a] Galantamine AN SR [EA] [a] Gamine XR [RW]

▪ RIVASTIGMINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4219

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

Clinical criteria:

Patient must have received six months of sole PBS-subsidised initial therapy with this drug, AND

Patient must demonstrate a clinically meaningful response to the initial treatment, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

rivastigmine 1.5 mg capsule, 56

2475G NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	87.64	38.30	Exelon [NV]

rivastigmine 13.3 mg/24 hours patch, 30

10538P NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	93.16	38.30	Exelon Patch 15 [NV]

rivastigmine 3 mg capsule, 56

2493F NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	87.64	38.30	Exelon [NV]

rivastigmine 4.5 mg capsule, 56

2494G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	87.64	38.30	Exelon [NV]

rivastigmine 4.6 mg/24 hours patch, 30

2477J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	93.16	38.30	Exelon Patch 5 [NV]

rivastigmine 6 mg capsule, 56

2526Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	87.64	38.30	Exelon [NV]

rivastigmine 9.5 mg/24 hours patch, 30

2551G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	93.16	38.30	Exelon Patch 10 [NV]

▪ RIVASTIGMINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, AND

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), AND

The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, AND

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), AND

The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;

(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;

(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;

(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;

(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;

(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

rivastigmine 1.5 mg capsule, 56

8497F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	87.64	38.30	Exelon [NV]

rivastigmine 13.3 mg/24 hours patch, 30

10541T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	93.16	38.30	Exelon Patch 15 [NV]

rivastigmine 3 mg capsule, 56

8498G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	87.64	38.30	Exelon [NV]

rivastigmine 4.5 mg capsule, 56

8499H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	87.64	38.30	Exelon [NV]

rivastigmine 4.6 mg/24 hours patch, 30

9161E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	93.16	38.30	Exelon Patch 5 [NV]

rivastigmine 6 mg capsule, 56

8500J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	87.64	38.30	Exelon [NV]

rivastigmine 9.5 mg/24 hours patch, 30

9162F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	93.16	38.30	Exelon Patch 10 [NV]

Other anti-dementia drugs

▪ MEMANTINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

4214

Moderately severe Alzheimer disease

Treatment Phase: Continuing

Clinical criteria:

Patient must have received six months of sole PBS-subsidised initial therapy with this drug, AND

Patient must demonstrate a clinically meaningful response to the initial treatment, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

memantine hydrochloride 10 mg tablet, 56

2492E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	57.42	38.30	[a] APO-Memantine [TX] [a] Memantine generichealth [GQ] [a] Memanxa [RW]	[a] Ebixa [LU] [a] Memantine RBX [RA]

memantine hydrochloride 20 mg tablet, 28

2513G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	57.42	38.30	[a] APO-Memantine [TX] [a] Memantine generichealth [GQ]	[a] Ebixa [LU] [a] Memantine RBX [RA]

▪ MEMANTINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 to 14, AND

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), AND

The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE of 10 to 14.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Authority required

Moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, AND

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), AND

The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 to 14 for reasons other than their Alzheimer disease, as specified below.

Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

(1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;

(2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;

(3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;

(4) Intellectual (developmental or acquired) disability, eg Down's syndrome;

(5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;

(6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

memantine hydrochloride 10 mg tablet, 56

1956Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	57.42	38.30	[a] APO-Memantine [TX] [a] Memantine generichealth [GQ] [a] Memanxa [RW]	[a] Ebixa [LU] [a] Memantine RBX [RA]

memantine hydrochloride 20 mg tablet, 28

9306T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	57.42	38.30	[a] APO-Memantine [TX] [a] Memantine generichealth [GQ]	[a] Ebixa [LU] [a] Memantine RBX [RA]

▪ OTHER NERVOUS SYSTEM DRUGS

PARASYMPATHOMIMETICS

Anticholinesterases

▪ PYRIDOSTIGMINE

PYRIDOSTIGMINE BROMIDE Tablet 10 mg, 50

2724J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*24.13	25.30	Mestinon [IA]

pyridostigmine bromide 180 mg tablet: modified release, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2608G	2	5	..	*133.75	38.30	Mestinon Timespan [IA]

pyridostigmine bromide 60 mg tablet, 150

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1959D	1	5	..	66.47	38.30	Mestinon [IA]

Choline esters

▪ BETHANECHOL

bethanechol chloride 10 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1062X NP	1	2	..	32.81	33.98	Uro-Carb [YN]

DRUGS USED IN ADDICTIVE DISORDERS

Drugs used in nicotine dependence

▪ BUPROPION

Note Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.
Note The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)
5518
Nicotine dependence
Treatment Phase: Completion of a short-term (9 weeks) course of treatment
Clinical criteria:
The treatment must be the sole PBS-subsidised therapy for this condition, AND
Patient must have previously been issued with an authority prescription for this drug during this current course of treatment, AND
Patient must be enrolled in a comprehensive support and counselling program, AND
Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period.

bupropion hydrochloride 150 mg tablet: modified release, 90

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8710K NP	1	..	..	164.73	38.30	Zyban [AS]

▪ BUPROPION

Note Clinical review is recommended within 2 to 3 weeks of the original prescription being requested.
Note The period between commencing a course of bupropion hydrochloride and varenicline tartrate must be at least 6 months.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)
5475
Nicotine dependence
Treatment Phase: Commencement of a short-term (9 weeks) course of treatment
Clinical criteria:
The treatment must be the sole PBS-subsidised therapy for this condition, AND
Patient must have indicated they are ready to cease smoking, AND
Patient must have entered a comprehensive support and counselling program, AND
Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period.
Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

Authority required (STREAMLINED)
5438
Nicotine dependence
Treatment Phase: Commencement of a short-term (9 weeks) course of treatment
Clinical criteria:
The treatment must be the sole PBS-subsidised therapy for this condition, AND
Patient must have indicated they are ready to cease smoking, AND
Patient must be entering a comprehensive support and counselling program during the consultation at which this prescription is written, AND
Patient must not receive more than 9 weeks of PBS-subsidised treatment with this drug per 12-month period.
Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

bupropion hydrochloride 150 mg tablet: modified release, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8465M NP	1	..	..	61.86	38.30	Zyban [AS]

▪ NICOTINE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit
Nicotine dependence
Clinical criteria:
The treatment must be the sole PBS-subsidised therapy for this condition, AND
Patient must have indicated they are ready to cease smoking, AND
Patient must have entered a comprehensive support and counselling program, AND
Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.
Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

Restricted benefit
Nicotine dependence
Clinical criteria:
The treatment must be the sole PBS-subsidised therapy for this condition, AND
Patient must have indicated they are ready to cease smoking, AND
Patient must be entering a comprehensive support and counselling program during the consultation at which this prescription is written, AND
Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.
Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

nicotine 14 mg/24 hours patch, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5572G NP	1	2	..	52.50	38.30	Nicotinell Step 2 [ON]

nicotine 21 mg/24 hours patch, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3414Q NP	1	2	..	52.50	38.30	Nicotinell Step 1 [ON]

nicotine 7 mg/24 hours patch, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5573H NP	1	2	..	52.50	38.30	Nicotinell Step 3 [ON]

▪ NICOTINE

Note Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period.
Benefit is improved if used in conjunction with a comprehensive support and counselling program.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit
Nicotine dependence
Clinical criteria:
The treatment must be the sole PBS-subsidised therapy for this condition.
Population criteria:
Patient must be an Aboriginal or a Torres Strait Islander person.

nicotine 21 mg/24 hours patch, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5571F NP	1	2	..	52.50	38.30	Nicotinell Step 1 [ON]

▪ NICOTINE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit
Nicotine dependence
Clinical criteria:
The treatment must be the sole PBS-subsidised therapy for this condition.
Population criteria:
Patient must be an Aboriginal or a Torres Strait Islander person.

Note Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period. Benefit is improved if used in conjunction with a comprehensive support and counselling program.

Restricted benefit

Nicotine dependence

Clinical criteria:

The treatment must be the sole PBS-subsidised therapy for this condition, AND

Patient must have indicated they are ready to cease smoking, AND

Patient must have entered a comprehensive support and counselling program, AND

Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

Restricted benefit

Nicotine dependence

Clinical criteria:

The treatment must be the sole PBS-subsidised therapy for this condition, AND

Patient must have indicated they are ready to cease smoking, AND

Patient must be entering a comprehensive support and counselling program during the consultation at which this prescription is written, AND

Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

nicotine 21 mg/24 hours patch, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5465P NP	1	2	..	52.50	38.30	Nicabate P [GC]

nicotine 25 mg/16 hours patch, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10076H NP	1	2	..	52.50	38.30	nicorette 16hr Invisipatch [JT]

▪ VARENICLINE

Note A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

Note A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Nicotine dependence

Treatment Phase: Completion of a short-term (24 weeks) course of treatment

Clinical criteria:

The treatment must be as an aid to achieving abstinence from smoking, AND

The treatment must be the sole PBS-subsidised therapy for this condition, AND

Patient must have previously been issued with an authority prescription for this drug during this current course of treatment, AND

Patient must have ceased smoking in the process of completing an initial 12-weeks or ceased smoking following an initial 12-weeks of PBS-subsidised treatment with this drug in the current course of treatment.

Treatment criteria:

Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

varenicline 1 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5469W NP	1	2	..	108.88	38.30	Champix [PF]

▪ VARENICLINE

Note A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.

Note A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Nicotine dependence

Treatment Phase: Continuation of a short-term (12 weeks or 24 weeks) course of treatment

Clinical criteria:

The treatment must be as an aid to achieving abstinence from smoking, AND

The treatment must be the sole PBS-subsidised therapy for this condition, AND

Patient must have previously been issued with an authority prescription for this drug during this current course of treatment.
Treatment criteria:
Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

varenicline 1 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9129L NP	2	..	..	*207.93	38.30	Champix [PF]

▪ VARENICLINE

Note A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.
Note The period between commencing varenicline and bupropion or a new course of varenicline must be at least 6 months.
Note A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required
Nicotine dependence
Treatment Phase: Commencement of a short-term (12 weeks or 24 weeks) course of treatment
Clinical criteria:
The treatment must be as an aid to achieving abstinence from smoking, AND
The treatment must be the sole PBS-subsidised therapy for this condition, AND
Patient must have indicated they are ready to cease smoking.
Treatment criteria:
Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time the Authority application is requested.
Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.
Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested.

varenicline 500 microgram tablet [11 tablets] (&) varenicline 1 mg tablet [42 tablets], 53

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9128K NP	‡1	..	..	93.93	38.30	Champix [PF]

Drugs used in alcohol dependence

▪ ACAMPROSATE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)
5366
Alcohol dependence
Clinical criteria:
The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence.

acamprosate calcium 333 mg tablet: enteric, 180

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8357W NP	1	1	..	148.74	38.30	Campral [AF]

▪ NALTREXONE

Caution Naltrexone hydrochloride is contraindicated in patients receiving opioid drugs.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required
Alcohol dependence
Clinical criteria:
The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence.

naltrexone hydrochloride 50 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8370M NP	1	1	..	127.92	38.30	[a] Naltrexone GH [GQ]	[a] ReVia [BQ]

OTHER NERVOUS SYSTEM DRUGS

Other nervous system drugs

▪ DIMETHYL FUMARATE

Note Special Pricing Arrangements apply.

Authority required

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND

The treatment must be as monotherapy, AND

Patient must have previously been issued with an authority prescription for this drug; OR

Patient must have been receiving treatment with this drug prior to 1 December 2013, AND

Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.

dimethyl fumarate 120 mg capsule: modified release, 14

2943X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	486.34	38.30	Tecfidera [BD]

▪ DIMETHYL FUMARATE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND

The treatment must be as monotherapy, AND

Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, AND

Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.

dimethyl fumarate 120 mg capsule: modified release, 14

2896K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	486.34	38.30	Tecfidera [BD]

▪ DIMETHYL FUMARATE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND

The treatment must be as monotherapy, AND

Patient must have previously been issued with an authority prescription for this drug; OR

Patient must have been receiving treatment with this drug prior to 1 December 2013, AND

Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.

dimethyl fumarate 240 mg capsule: modified release, 56

2966D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1870.47	38.30	Tecfidera [BD]

▪ RILUZOLE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required
Amyotrophic lateral sclerosis
Treatment Phase: Initial treatment
Clinical criteria:
The condition must be diagnosed by a neurologist, AND
Patient must not have had the disease for more than 5 years, AND
Patient must have at least 60 percent of predicted forced vital capacity within the 2 months before commencing therapy with this drug, AND
Patient must be ambulatory; OR
Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, AND
Patient must not have undergone a tracheostomy, AND
Patient must not have experienced respiratory failure.
The date of diagnosis and the date and results of spirometry (in terms of percent of predicted forced vital capacity) must be supplied with the initial authority application.

Authority required
Amyotrophic lateral sclerosis
Treatment Phase: Continuing treatment
Clinical criteria:
Patient must have previously been issued with an authority prescription for this drug, AND
Patient must be ambulatory; OR
Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, AND
Patient must not have undergone a tracheostomy, AND
Patient must not have experienced respiratory failure.

riluzole 50 mg tablet, 56

8664B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	303.17	38.30	[a] APO-Riluzole [TX] [a] Rilutek [SW] [a] Riluzole Winthrop [WA]	[a] Pharmacor Riluzole [CR] [a] Riluzole Sandoz [SZ]

▪ TETRABENAZINE

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
5340
Hyperkinetic extrapyramidal disorders

tetrabenazine 25 mg tablet, 112

1330B NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	337.93	38.30	iNova Pharmaceuticals (Australia) Pty Ltd [IA]

▪ ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

▪ ANTIPROTOZOALS

AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES

Other agents against amoebiasis and other protozoal diseases

▪ ATOVAQUONE

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
5609
Mild to moderate Pneumocystis carinii pneumonia
Population criteria:
Patient must be an adult, AND
Patient must be intolerant of trimethoprim/sulfamethoxazole therapy.

atovaquone 750 mg/5 mL oral liquid, 210 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8300W NP	‡1	..	..	976.18	38.30	Wellvone [AS]

▪ PYRIMETHAMINE

pyrimethamine 25 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1966L NP	1	..	..	18.65	19.82	Daraprim [RW]

ANTIMALARIALS

Biguanides

▪ ATOVAQUONE + PROGUANIL

Note This drug is not PBS-subsidised for prophylaxis of malaria.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Confirmed or suspected Plasmodium falciparum malaria

Clinical criteria:

The treatment must be used where quinine containing regimens are inappropriate.

Population criteria:

Patient must be aged 3 years or older.

atovaquone 250 mg + proguanil hydrochloride 100 mg tablet, 12

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9439T NP	1	..	..	65.49	38.30	Malarone [GK]

Methanolquinolines

▪ QUININE

Caution Severe thrombocytopenia has been reported with this drug.

Authority required (STREAMLINED)

5633

Malaria

quinine sulfate 300 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1975Y NP	1	2	..	17.13	18.30	Quinate [RW]

Artemisinin and derivatives, combinations

▪ ARTEMETHER + LUMEFANTRINE

Note This drug is not PBS-subsidised for prophylaxis of malaria.

Restricted benefit

Confirmed or suspected Plasmodium falciparum malaria

Clinical criteria:

Patient must be unable to swallow a solid dosage form of artemether with lumefantrine.

artemether 20 mg + lumefantrine 120 mg tablet: dispersible, 18

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5296R	1	..	..	88.57	38.30	Riamet 20mg/120mg Dispersible [NV]

▪ ARTEMETHER + LUMEFANTRINE

Note This drug is not PBS-subsidised for prophylaxis of malaria.

Restricted benefit

Confirmed or suspected Plasmodium falciparum malaria

artemether 20 mg + lumefantrine 120 mg tablet, 24

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9498X	1	..	..	88.57	38.30	Riamet [NV]

▪ ANTHELMINTICS

ANTITREMATODALS

Quinoline derivatives and related substances

▪ PRAZIQUANTEL

Authority required (STREAMLINED)
5659
Schistosomiasis

praziquantel 600 mg tablet, 8

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9447F NP	1	..	..	38.87	38.30	Biltricide [BN]

ANTINEMATODAL AGENTS

Benzimidazole derivatives

▪ ALBENDAZOLE

Authority required (STREAMLINED)
5607
Hydatid disease
Clinical criteria:
The treatment must be in conjunction with surgery; OR
The treatment must be used when a surgical cure cannot be achieved; OR
The treatment must be used when surgery cannot be used.

albendazole 400 mg tablet: chewable, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8459F	1	2	..	164.86	38.30	Eskazole [AS]

▪ ALBENDAZOLE

Authority required (STREAMLINED)
5680
Tapeworm infestation

albendazole 200 mg tablet: chewable, 6

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8503M NP	1	1	..	32.46	33.63	Zentel [AS]

▪ ALBENDAZOLE

Authority required (STREAMLINED)
5817
Whipworm infestation
Population criteria:
Patient must be an Aboriginal or a Torres Strait Islander person.
Authority required (STREAMLINED)
5712
Strongyloidiasis
Authority required (STREAMLINED)
5797
Hookworm infestation

albendazole 200 mg tablet: chewable, 6

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9047E NP	1	..	..	32.46	33.63	Zentel [AS]

Tetrahydropyrimidine derivatives

▪ PYRANTEL

pyrantel 125 mg tablet, 6

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3047J NP	1	..	..	17.17	18.34	Anthel 125 [AF]

pyrantel 250 mg tablet, 6

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3048K NP	1	..	..	23.94	25.11	Anthel 250 [AF]

Avermectines

▪ IVERMECTIN

Authority required (STREAMLINED)
4319
Onchocerciasis

ivermectin 3 mg tablet, 4

8359Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	30.98	32.15	Stromectol [MK]

▪ IVERMECTIN

Authority required (STREAMLINED)

4328

Strongyloidiasis

Authority required (STREAMLINED)

4565

Crusted (Norwegian) scabies

Clinical criteria:

The condition must be established by clinical and/or parasitological examination, AND

Patient must be undergoing topical therapy for this condition; OR

Patient must have a contraindication to topical treatment.

Population criteria:

Patient must weigh 15 kg or over, AND

Patient must be 5 years of age or older.

Authority required (STREAMLINED)

4566

Human sarcoptic scabies

Clinical criteria:

The condition must be established by clinical and/or parasitological examination, AND

Patient must have completed and failed sequential treatment with topical permethrin and benzyl benzoate and finished the most recent course of topical therapy at least 4 weeks prior to initiating oral therapy; OR

Patient must have a contraindication to topical treatment.

Population criteria:

Patient must weigh 15 kg or over, AND

Patient must be 5 years of age or older.

Note This drug is not PBS-subsidised for first line treatment of typical scabies.

ivermectin 3 mg tablet, 4

2868Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	2	..	*51.55	38.30	Stromectol [MK]

▪ ECTOPARASITICIDES, INCL. SCABICIDES, INSECTICIDES AND REPELLENTS

ECTOPARASITICIDES, INCL. SCABICIDES

Pyrethrines, incl. synthetic compounds

▪ PERMETHRIN

permethrin 5% cream, 30 g

3054R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	1	..	18.97	20.14	Lyclear [JT]

▪ RESPIRATORY SYSTEM

▪ NASAL PREPARATIONS

DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE

Other nasal preparations

▪ MUPIROCIN

Note No applications for increased maximum quantities and/or repeats will be authorised.

Authority required (STREAMLINED)

3136

Nasal colonisation with Staphylococcus aureus in an Aboriginal or a Torres Strait Islander person

mupirocin 2% (20 mg/g) ointment, 3 g

9440W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	..	..	22.17	23.34	Bactroban [GK]

▪ DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

ADRENERGICS, INHALANTS

Selective beta-2-adrenoreceptor agonists

▪ EFORMOTEROL

Restricted benefit

Patients with frequent episodes of asthma who are currently receiving treatment with oral corticosteroids

Restricted benefit

Patients with frequent episodes of asthma who are currently receiving treatment with optimal doses of inhaled corticosteroids

eformoterol fumarate dihydrate 12 microgram inhalation: powder for, 60 capsules

8136F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	35.96	37.13	Foradile [NV]

eformoterol fumarate dihydrate 12 microgram/actuation inhalation: powder for, 60 actuations

8240Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	35.21	36.38	Oxis Turbuhaler [AP]

eformoterol fumarate dihydrate 6 microgram/actuation inhalation: powder for, 60 actuations

8239P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	26.91	28.08	Oxis Turbuhaler [AP]

▪ INDACATEROL

Note Indacaterol is not PBS-subsidised for the treatment of asthma.

Restricted benefit

Chronic obstructive pulmonary disease

indacaterol 150 microgram inhalation: powder for, 30 capsules

5134F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	61.30	38.30	Onbrez [NV]

indacaterol 300 microgram inhalation: powder for, 30 capsules

5137J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	61.30	38.30	Onbrez [NV]

▪ SALBUTAMOL

salbutamol 100 microgram/actuation inhalation: pressurised, 200 actuations

8288F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*16.85	18.02	[a] Asmol CFC-free [AL]
			[B]2.04	*18.89	18.02	[a] Ventolin CFC-free [GK]

salbutamol 200 microgram inhalation: powder for, 128 capsules

10143W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	4	..	*21.17	22.34	Ventolin Rotacaps [GK]

▪ SALBUTAMOL

Restricted benefit

Patients unable to achieve co-ordinated use of other metered dose inhalers containing this drug

salbutamol Oral pressurised inhalation in breath actuated device 100 micrograms (base) per dose (200 doses), CFC-free formulation, 1

8354Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*38.41	38.30	Airomir Autohaler [IA]

▪ SALBUTAMOL

Restricted benefit

Asthma in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer

Restricted benefit

Chronic obstructive pulmonary disease in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer

salbutamol 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules

2000G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.43	19.60	[a] APO-Salbutamol [TX]	[a] Butamol 2.5 [QA]
						[a] GenRx Salbutamol [GX]	[a] Pharmacor Salbutamol 2.5 [CR]
						[a] Salbutamol Actavis [EA]	[a] Salbutamol Sandoz [SZ]
			[B]0.50	*18.93	19.60	[a] Asmol 2.5 uni-dose [AF]	
			[B]1.04	*19.47	19.60	[a] Ventolin Nebules [GK]	

salbutamol 5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules

2001H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*18.85	20.02	[a] APO-Salbutamol [TX] [a] GenRx Salbutamol [GX] [a] Salbutamol Actavis [EA]	[a] Butamol 5 [QA] [a] Pharmacor Salbutamol 5 [CR] [a] Salbutamol Sandoz [SZ]
			[B]0.50	*19.35	20.02	[a] Asmol 5 uni-dose [AF]	
			[B]1.00	*19.85	20.02	[a] Ventolin Nebules [GK]	

▪ SALMETEROL

Restricted benefit

Patients with frequent episodes of asthma who are currently receiving treatment with oral corticosteroids

Restricted benefit

Patients with frequent episodes of asthma who are currently receiving treatment with optimal doses of inhaled corticosteroids

salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations

8141L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	35.96	37.13	Serevent Accuhaler [GK]

▪ TERBUTALINE

terbutaline sulfate 500 microgram/actuation inhalation: powder for, 100 actuations

2817G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*19.87	21.04	Bricanyl Turbuhaler [AP]

Adrenergics in combination with corticosteroids or other drugs, excl. anticholinergics

▪ BUDESONIDE + EFORMOTEROL

Restricted benefit

Asthma

Clinical criteria:

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR

Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR

Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist and require single maintenance and reliever therapy.

Population criteria:

Patient must be aged 12 years or over.

budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation inhalation: powder for, 120 actuations

8796Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	53.97	38.30	Symbicort Turbuhaler 100/6 [AP]

budesonide 200 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation inhalation: powder for, 120 actuations

8625Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	58.01	38.30	Symbicort Turbuhaler 200/6 [AP]

▪ BUDESONIDE + EFORMOTEROL

Restricted benefit

Asthma

Clinical criteria:

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; OR

Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR

Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist.

Population criteria:

Patient must be aged 12 years or over.

budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation inhalation: pressurised, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10015D NP	2	5	..	*55.63	38.30	Symbicort Rapihaler 100/3 [AP]

budesonide 50 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation inhalation: pressurised, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10024N NP	2	5	..	*51.81	38.30	Symbicort Rapihaler 50/3 [AP]

▪ BUDESONIDE + EFORMOTEROL

Restricted benefit

Asthma

Clinical criteria:

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

Patient must be aged 12 years or over.

Note Symbicort 400/12 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, AND

Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, AND

The treatment must be for symptomatic treatment.

Note Patient must not be on a concomitant single agent long-acting beta-2 agonist.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

budesonide 400 microgram/actuation + eformoterol fumarate dihydrate 12 microgram/actuation inhalation: powder for, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8750M NP	‡1	5	..	85.52	38.30	Symbicort Turbuhaler 400/12 [AP]

▪ BUDESONIDE + EFORMOTEROL

Restricted benefit

Asthma

Clinical criteria:

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

Patient must be aged 12 years or over.

Note Unlike Symbicort Turbuhaler 200/6, Symbicort Rapihaler 200/6 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy as the approved Product Information does not specify such use.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, AND

Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, AND

The treatment must be for symptomatic treatment.

Note Patient must not be on a concomitant single agent long-acting beta-2 agonist.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

budesonide 200 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation inhalation: pressurised, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10018G NP	2	5	..	*81.79	38.30	Symbicort Rapihaler 200/6 [AP]

▪ FLUTICASONE + EFORMOTEROL

Note Flutiform is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

Note Flutiform is not indicated or PBS-subsidised for bronchodilator therapy in COPD.

Restricted benefit

Asthma

Clinical criteria:

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

Patient must be aged 12 years or over.

fluticasone propionate 125 microgram/actuation + eformoterol fumarate dihydrate 5 microgram/actuation inhalation: pressurised, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10007Q NP	‡1	5	..	50.11	38.30	flutiform 125/5 [MF]

fluticasone propionate 250 microgram/actuation + eformoterol fumarate dihydrate 10 microgram/actuation inhalation: pressurised, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10008R NP	‡1	5	..	67.64	38.30	flutiform 250/10 [MF]

fluticasone propionate 50 microgram/actuation + eformoterol fumarate dihydrate 5 microgram/actuation inhalation: pressurised, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2827T NP	‡1	5	..	40.75	38.30	flutiform 50/5 [MF]

▪ FLUTICASONE + SALMETEROL

Restricted benefit

Asthma

Clinical criteria:

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

Patient must be aged 4 years or older.

fluticasone propionate 100 microgram/actuation + salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8430Q NP	‡1	5	..	46.70	38.30	Seretide Accuhaler 100/50 [GK]

fluticasone propionate 125 microgram/actuation + salmeterol 25 microgram/actuation inhalation: pressurised, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8518H NP	‡1	5	..	54.65	38.30	Seretide MDI 125/25 [GK]

fluticasone propionate 250 microgram/actuation + salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8431R NP	‡1	5	..	54.65	38.30	Seretide Accuhaler 250/50 [GK]

fluticasone propionate 50 microgram/actuation + salmeterol 25 microgram/actuation inhalation: pressurised, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8517G NP	‡1	5	..	46.70	38.30	Seretide MDI 50/25 [GK]

▪ FLUTICASONE + SALMETEROL

Restricted benefit

Asthma

Clinical criteria:

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

Patient must be aged 4 years or older.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, AND

Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, AND

The treatment must be for symptomatic treatment.

Note Patient must not be on a concomitant single agent long-acting beta-2 agonist.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

fluticasone propionate 250 microgram/actuation + salmeterol 25 microgram/actuation inhalation: pressurised, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8519J NP	‡1	5	..	70.30	38.30	Seretide MDI 250/25 [GK]

fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8432T NP	‡1	5	..	70.30	38.30	Seretide Accuhaler 500/50 [GK]

▪ FLUTICASONE + VILANTEROL

Note This drug is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Restricted benefit

Asthma

Clinical criteria:

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

Patient must be aged 12 years or over.

fluticasone furoate 200 microgram/actuation + vilanterol 25 microgram/actuation inhalation: powder for, 30 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10167D NP	‡1	5	..	70.95	38.30	Breo Ellipta 200/25 [GK]

▪ FLUTICASONE + VILANTEROL

Restricted benefit

Asthma

Clinical criteria:

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

Patient must be aged 12 years or over.

Note This drug is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy, AND

Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy, AND

The treatment must be for symptomatic treatment.

Note Patient must not be on a concomitant single agent long-acting beta-2 agonist.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

fluticasone furoate 100 microgram/actuation + vilanterol 25 microgram/actuation inhalation: powder for, 30 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10199T NP	‡1	5	..	55.45	38.30	Breo Ellipta 100/25 [GK]

Adrenergics in combination with anticholinergics

▪ ACLIDINIUM + EFORMOTEROL

Note The treatment must not be used in combination with an ICS/LABA, or LAMA or LABA monotherapy.

Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, eformoterol or vilanterol.

Note This product is not PBS-subsidised for the treatment of asthma.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Authority required (STREAMLINED)

5763

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

Patient must have been stabilised on a combination of a long acting muscarinic antagonist and long acting beta-2 agonist.

aclidinium 340 microgram/actuation + eformoterol fumarate dihydrate 12 microgram/actuation inhalation: powder for, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10565C NP	‡1	5	..	90.51	38.30	Brimica Genuair [FK]

▪ INDACATEROL + GLYCOPYRRONIUM

Note The treatment must not be used in combination with an ICS/LABA, or LAMA or LABA monotherapy.
Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
Note A LABA includes olodaterol, indacaterol, salmeterol, eformoterol or vilanterol.
Note This product is not PBS-subsidised for the treatment of asthma.
Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Authority required (STREAMLINED)
5763
Chronic obstructive pulmonary disease (COPD)
Clinical criteria:
Patient must have been stabilised on a combination of a long acting muscarinic antagonist and long acting beta-2 agonist.

indacaterol 110 microgram + glycopyrronium 50 microgram inhalation: powder for, 30 capsules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10156M NP	1	5	..	91.89	38.30	ultibro breezhaler 110/50 [NV]

▪ TIOTROPIUM + OLODATEROL

Note The treatment must not be used in combination with an ICS/LABA, or LAMA or LABA monotherapy.
Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
Note A LABA includes olodaterol, indacaterol, salmeterol, eformoterol or vilanterol.
Note This product is not PBS-subsidised for the treatment of asthma.
Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Authority required (STREAMLINED)
5763
Chronic obstructive pulmonary disease (COPD)
Clinical criteria:
Patient must have been stabilised on a combination of a long acting muscarinic antagonist and long acting beta-2 agonist.

tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation: solution, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10557P NP	‡1	5	..	89.34	38.30	Spiolto Respimat [BY]

▪ UMECLIDINIUM + VILANTEROL

Note The treatment must not be used in combination with an ICS/LABA, or LAMA or LABA monotherapy.
Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.
Note A LABA includes olodaterol, indacaterol, salmeterol, eformoterol or vilanterol.
Note This product is not PBS-subsidised for the treatment of asthma.
Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Authority required (STREAMLINED)
5763
Chronic obstructive pulmonary disease (COPD)
Clinical criteria:
Patient must have been stabilised on a combination of a long acting muscarinic antagonist and long acting beta-2 agonist.

umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation inhalation: powder for, 30 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10188F NP	‡1	5	..	91.89	38.30	Anoro Ellipta 62.5/25 [GK]

OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS

Glucocorticoids

▪ BECLOMETHASONE

beclomethasone dipropionate 100 microgram/actuation inhalation: pressurised, 200 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8407L NP	‡1	5	..	32.76	33.93	Qvar 100 [IA]

beclomethasone dipropionate 50 microgram/actuation inhalation: pressurised, 200 actuations

8406K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	21.05	22.22	Qvar 50 [IA]

▪ BECLOMETHASONE

Restricted benefit

Patients unable to achieve co-ordinated use of other metered dose inhalers containing this drug

BECLOMETHASONE DIPROPIONATE Oral pressurised inhalation in breath actuated device 100 micrograms per dose (200 doses), CFC-free formulation, 1

8409N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	37.44	38.30	Qvar 100 Autohaler [IA]

BECLOMETHASONE DIPROPIONATE Oral pressurised inhalation in breath actuated device 50 micrograms per dose (200 doses), CFC-free formulation, 1

8408M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	28.14	29.31	Qvar 50 Autohaler [IA]

▪ BUDESONIDE

budesonide 100 microgram/actuation inhalation: powder for, 200 actuations

2070Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	24.40	25.57	Pulmicort Turbuhaler [AP]

budesonide 200 microgram/actuation inhalation: powder for, 200 actuations

2071B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	30.78	31.95	Pulmicort Turbuhaler [AP]

budesonide 400 microgram/actuation inhalation: powder for, 200 actuations

2072C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	43.60	38.30	Pulmicort Turbuhaler [AP]

▪ BUDESONIDE

Authority required (STREAMLINED)

1351

Severe chronic asthma in patients who require long-term steroid therapy and who are unable to use other forms of inhaled steroid therapy

budesonide 1 mg/2 mL inhalation: solution, 30 x 2 mL ampoules

2066R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	46.60	38.30	Pulmicort Respules [AP]

budesonide 500 microgram/2 mL inhalation: solution, 30 x 2 mL ampoules

2065Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	36.40	37.57	Pulmicort Respules [AP]

▪ CICLESONIDE

ciclesonide 160 microgram/actuation inhalation: pressurised, 120 actuations

8854B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	40.18	38.30	Alvesco 160 [NQ]

ciclesonide 80 microgram/actuation inhalation: pressurised, 120 actuations

8853Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	26.72	27.89	Alvesco 80 [NQ]

▪ FLUTICASONE

fluticasone propionate 100 microgram/actuation inhalation: powder for, 60 actuations

8147T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	19.24	20.41	Flixotide Junior Accuhaler [GK]

fluticasone propionate 125 microgram/actuation inhalation: pressurised, 120 actuations

8345F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	30.45	31.62	Flixotide [GK]

fluticasone propionate 250 microgram/actuation inhalation: powder for, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8148W NP	‡1	5	..	30.45	31.62	Flixotide Accuhaler [GK]

fluticasone propionate 250 microgram/actuation inhalation: pressurised, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8346G NP	‡1	1	..	47.29	38.30	Flixotide [GK]

fluticasone propionate 50 microgram/actuation inhalation: pressurised, 120 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8516F NP	‡1	5	..	19.24	20.41	Flixotide Junior [GK]

fluticasone propionate 500 microgram/actuation inhalation: powder for, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8149X NP	‡1	1	..	47.29	38.30	Flixotide Accuhaler [GK]

Anticholinergics

▪ ACLIDINIUM

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

aclidinium 322 microgram/actuation inhalation: powder for, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10124W NP	‡1	5	..	61.30	38.30	Bretaris Genuair [FK]

▪ GLYCOPYRRONIUM

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

glycopyrronium 50 microgram inhalation: powder for, 30 capsules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10059K NP	1	5	..	61.30	38.30	seebri breezhaler [NV]

▪ IPRATROPIUM

ipratropium bromide 20 microgram/actuation inhalation: pressurised, 200 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8671J NP	2	5	..	*34.27	35.44	Atrovent [BY]

▪ IPRATROPIUM

Restricted benefit

Asthma in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer

Restricted benefit

Chronic obstructive pulmonary disease in patients unable to use this drug delivered from an oral pressurised inhalation device via a spacer

ipratropium bromide 250 microgram/mL inhalation: solution, 30 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1542E NP	2	5	..	*29.15	30.32	[a] Aeron 250 [QA] [a] Ipratrin [AF]	[a] APO-Ipratropium [TX]
			[B]0.50	*29.65	30.32	[a] Atrovent [BY]	

ipratropium bromide 500 microgram/mL inhalation: solution, 30 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8238N NP	2	5	..	*32.55	33.72	[a] Aeron 500 [QA] [a] Ipratrin Adult [AF]	[a] APO-Ipratropium [TX]
			[B]0.50	*33.05	33.72	[a] Atrovent Adult [BY]	

▪ TIOTROPIUM

Restricted benefit

Bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease

Treatment Phase: Long-term maintenance treatment

tiotropium 2.5 microgram/actuation inhalation: solution, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10509D NP	‡1	5	..	58.75	38.30	Spiriva Respimat [BY]

▪ TIOTROPIUM

Restricted benefit

Chronic obstructive pulmonary disease

tiotropium 18 microgram inhalation: powder for, 30 capsules

8626B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	58.75	38.30	Spiriva [BY]

▪ UMECLIDINIUM

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

umeclidinium 62.5 microgram/actuation inhalation: powder for, 30 actuations

10187E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	61.30	38.30	Incruse Ellipta [GK]

Antiallergic agents, excl. corticosteroids

▪ CROMOGLYCATE

cromoglycate sodium 1 mg/actuation inhalation: pressurised, 200 actuations

8767K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	33.97	35.14	Intal CFC-Free [SW]

cromoglycate sodium 20 mg inhalation: powder for, 100 capsules

2878L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	32.15	33.32	Intal Spincaps [EA]

cromoglycate sodium 5 mg/actuation inhalation: pressurised, 112 actuations

8334P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	38.15	38.30	Intal Forte CFC-Free [SW]

▪ NEDOCROMIL

nedocromil sodium 2 mg/actuation inhalation: pressurised, 112 actuations

8365G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	38.05	38.30	Tilade CFC-Free [SW]

ADRENERGICS FOR SYSTEMIC USE

Alpha- and beta-adrenoreceptor agonists

▪ ADRENALINE

adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules

1016L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	1	..	21.91	23.08	Link Medical Products Pty Ltd [LM]

adrenaline 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules

5004J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	21.91	23.08	Link Medical Products Pty Ltd [LM]

▪ ADRENALINE

Caution EpiPen and Anapen products have different administration techniques and should not be prescribed to the same patient without training in their use.

Note The auto-injector should be provided in the framework of a comprehensive anaphylaxis prevention program and an emergency action plan including training in recognition of the symptoms of anaphylaxis and the use of the auto-injector device. (For further information see the Australasian Society of Clinical Immunology and Allergy website at www.allergy.org.au.)

Note Authority approvals will be limited to a maximum quantity of 2 auto-injectors (Anapen or EpiPen) at any one time.

Note No applications for repeats will be authorised.

Authority required

Acute allergic reaction with anaphylaxis

Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment

Clinical criteria:

Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a clinical immunologist; OR

Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with an allergist; OR

Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a paediatrician; OR
Patient must have been assessed to be at significant risk of anaphylaxis by, or in consultation with a respiratory physician.
The name of the specialist consulted must be provided at the time of application for initial supply.

Authority required

Acute allergic reaction with anaphylaxis
Treatment Phase: Initial sole PBS-subsidised supply for anticipated emergency treatment
Clinical criteria:
Patient must have been discharged from hospital or an emergency department after treatment with adrenaline for acute allergic reaction with anaphylaxis.

Authority required

Acute allergic reaction with anaphylaxis
Treatment Phase: Continuing sole PBS-subsidised supply for anticipated emergency treatment
Clinical criteria:
Patient must have previously been issued with an authority prescription for this drug.

adrenaline 150 microgram/0.3 mL injection, 0.3 mL syringe

3408J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	96.43	38.30	Anapen Junior [LM]

adrenaline 150 microgram/0.3 mL injection, 0.3 mL syringe

8697R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	96.43	38.30	EpiPen Jr. [AL]

adrenaline 300 microgram/0.3 mL injection, 0.3 mL syringe

3409K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	96.43	38.30	Anapen [LM]

adrenaline 300 microgram/0.3 mL injection, 0.3 mL syringe

8698T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	96.43	38.30	EpiPen [AL]

Selective beta-2-adrenoreceptor agonists

▪ SALBUTAMOL

salbutamol 2 mg/5 mL oral liquid, 150 mL

1103C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*24.15	25.32	Ventolin [GK]

▪ TERBUTALINE

terbutaline sulfate 500 microgram/mL injection, 5 x 1 mL ampoules

1034K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	30.39	31.56	Bricanyl [AP]

OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

Xanthines

▪ THEOPHYLLINE

Caution Because of variable effects of food on absorption of sustained release theophylline preparations, patients stabilised on one brand should not be changed to another without appropriate monitoring.

Note Continuing Therapy Only:
For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

theophylline 133.3 mg/25 mL oral liquid, 500 mL

2614N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	16.01	17.18	Nuelin [IA]

theophylline 200 mg tablet: modified release, 100

8230E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	15.16	16.33	Nuelin-SR 200 [IA]

theophylline 250 mg tablet: modified release, 100

2634P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	16.12	17.29	Nuelin-SR 250 [IA]

theophylline 300 mg tablet: modified release, 100

8231F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	17.27	18.44	Nuelin-SR 300 [IA]

Leukotriene receptor antagonists

▪ MONTELUKAST

Note Montelukast sodium is not PBS-subsidised for use in a child aged 2 to 5 years with moderate to severe asthma. It is not intended as an alternative for a child aged 2 to 5 years who requires a corticosteroid as a preventer medication. Montelukast sodium is not subsidised in a child aged 2 to 5 years for use in combination with other preventer medications. PBS subsidy for montelukast sodium will therefore cease for a child aged 2 to 5 years who requires a preventer medication in addition to montelukast sodium.

Note No applications for increased maximum quantities and/or repeats will be authorised.

Authority required (STREAMLINED)

2617

First-line preventer medication, as the single preventer agent for children aged 2 to 5 years with frequent intermittent or mild persistent asthma, as an alternative to sodium cromoglycate or nedocromil sodium

montelukast 4 mg tablet: chewable, 28

8627C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	23.74	24.91	[a] APO-Montelukast [TX] [a] Chem mart Montelukast [CH] [a] Montair 4 [ED] [a] Montelukast GH [GQ] [a] Pharmacor Montelukast 4 [CR] [a] Terry White Chemists Montelukast [TW]	[a] Auro-Montelukast Tabs 4 [DO] [a] Lukair [FR] [a] Montelukast AN [EA] [a] Montelukast Sandoz 4 [SZ] [a] Respikast 4 [RW] [a] T Lukast [AF]
			[B]2.00	25.74	24.91	[a] Singulair [MK]	

▪ MONTELUKAST

Note Montelukast sodium is not PBS-subsidised for use in a patient aged 15 years or older, or for use in addition to a long-acting beta-agonist in any age group, or for use as a single second line preventer, as an alternative to corticosteroids, in a child aged 6 to 14 years with moderate to severe asthma.

Note No applications for increased maximum quantities and/or repeats will be authorised.

Authority required (STREAMLINED)

2618

First-line preventer medication, as the single preventer agent for children aged 6 to 14 years with frequent intermittent or mild persistent asthma, as an alternative to sodium cromoglycate or nedocromil sodium

Authority required (STREAMLINED)

3217

Prevention of exercise-induced asthma, as an alternative to adding salmeterol xinafoate or eformoterol fumarate, in a child aged 6 to 14 years whose asthma is otherwise well controlled while receiving optimal dose inhaled corticosteroid, but who requires short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms

montelukast 5 mg tablet: chewable, 28

8628D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	22.95	24.12	[a] APO-Montelukast [TX] [a] Chem mart Montelukast [CH] [a] Montair 5 [ED] [a] Montelukast GH [GQ] [a] Pharmacor Montelukast 5 [CR] [a] Singulair [MK] [a] T Lukast [AF]	[a] Auro-Montelukast Tabs 5 [DO] [a] Lukair [FR] [a] Montelukast AN [EA] [a] Montelukast Sandoz 5 [SZ] [a] Respikast 5 [RW] [a] Terry White Chemists Montelukast [TW]

▪ COUGH AND COLD PREPARATIONS

COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS

Opium alkaloids and derivatives

▪ CODEINE

codeine phosphate 30 mg tablet, 20

1214X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	19.73	20.90	Fawns and McAllan Proprietary Limited [FM]

ANTIHISTAMINES FOR SYSTEMIC USE

ANTIHISTAMINES FOR SYSTEMIC USE

Phenothiazine derivatives

PROMETHAZINE

promethazine hydrochloride 50 mg/2 mL injection, 5 x 2 mL ampoules

1948M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*38.01	38.30	Hospira Pty Limited [HH]

SENSORY ORGANS

OPHTHALMOLOGICALS

ANTIINFECTIVES

Antibiotics

AZITHROMYCIN

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit
Trachoma

azithromycin 200 mg/5 mL oral liquid: powder for, 15 mL

8201P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	..	..	#25.51	27.04	Zithromax [PF]

azithromycin 500 mg tablet, 2

8336R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	15.30	16.47	[a] APO-Azithromycin [TX] [a] Azithromycin Sandoz [SZ] [a] Terry White Chemists Azithromycin [TW]	[a] Azithromycin-GA [EA] [a] Chem mart Azithromycin [CH] [a] Zithromax [PF]

GENTAMICIN

Restricted benefit
Perioperative use in ophthalmic surgery
Restricted benefit
Suspected Pseudomonal eye infection

gentamicin 0.3% eye drops, 5 mL

5566Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
OP	‡1	2	..	20.74	21.91	Genoptic [AG]

GENTAMICIN

Restricted benefit
Invasive ocular infection
Restricted benefit
Perioperative use in ophthalmic surgery
Restricted benefit
Suspected Pseudomonal eye infection

gentamicin 0.3% eye drops, 5 mL

1441W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	20.74	21.91	Genoptic [AG]

TOBRAMYCIN

Restricted benefit
Perioperative use in ophthalmic surgery
Restricted benefit
Suspected Pseudomonal eye infection

tobramycin 0.3% eye drops, 5 mL

5569D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
OP	‡1	2	..	21.04	22.21	Tobrex [AQ]

tobramycin 0.3% eye ointment, 3.5 g

5570E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
OP	‡1	..	..	23.60	24.77	Tobrex [AQ]

▪ TOBRAMYCIN

Restricted benefit

Invasive ocular infection

Restricted benefit

Perioperative use in ophthalmic surgery

Restricted benefit

Suspected Pseudomonal eye infection

tobramycin 0.3% eye drops, 5 mL

2328M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	21.04	22.21	Tobrex [AQ]

tobramycin 0.3% eye ointment, 3.5 g

2329N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	23.60	24.77	Tobrex [AQ]

Antivirals

▪ ACICLOVIR

Restricted benefit

Herpes simplex keratitis

aciclovir 3% eye ointment, 4.5 g

5501M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	‡1	..	..	37.41	38.30	AciVision [DZ]	Zovirax [GK]

▪ ACICLOVIR

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Herpes simplex keratitis

aciclovir 3% eye ointment, 4.5 g

1002R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	..	..	37.41	38.30	AciVision [DZ]	Zovirax [GK]

Fluoroquinolones

▪ CIPROFLOXACIN

Authority required

Bacterial keratitis

Treatment criteria:

Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

ciprofloxacin 0.3% eye drops, 5 mL

1217C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*29.61	30.78	[a] CiloQuin [IQ]
			[B]3.16	*32.77	30.78	[a] Ciloxan [AQ]

▪ CIPROFLOXACIN

Authority required

Bacterial keratitis

Treatment criteria:

Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

ciprofloxacin 0.3% eye drops, 5 mL

5564W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
OP	2	..	..	*29.61	30.78	[a] CiloQuin [IQ]
			[B]3.16	*32.77	30.78	[a] Ciloxan [AQ]

▪ OFLOXACIN

Authority required

Bacterial keratitis

Treatment criteria:
Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

ofloxacin 0.3% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5567B OP	2	..	..	*34.29	35.46	Ocuflox [AG]

▪ OFLOXACIN

Authority required
Bacterial keratitis
Treatment criteria:
Must be treated by an ophthalmologist or in consultation with an ophthalmologist.

ofloxacin 0.3% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8383F	2	..	..	*34.29	35.46	Ocuflox [AG]

ANTIINFLAMMATORY AGENTS

Corticosteroids, plain

▪ DEXAMETHASONE

DEXAMETHASONE Eye drops 1 mg per mL (0.1%), 5 mL, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1288T NP	‡1	2	..	14.06	15.23	Maxidex [AQ]

▪ DEXAMETHASONE

Note No applications for increased maximum quantities will be authorised.
Note No applications for increased repeats will be authorised.

DEXAMETHASONE Eye drops 1 mg per mL (0.1%), 5 mL, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5565X OP	‡1	..	..	14.06	15.23	Maxidex [AQ]

▪ FLUOROMETHOLONE

fluorometholone 0.1% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1204J NP	‡1	5	..	13.88	15.05	Flucon [AQ]	FML Liquifilm [AG]

▪ FLUOROMETHOLONE

Note No applications for increased maximum quantities will be authorised.
Note No applications for increased repeats will be authorised.

fluorometholone 0.1% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5513E OP	‡1	..	..	13.88	15.05	Flucon [AQ]	FML Liquifilm [AG]

▪ FLUOROMETHOLONE ACETATE

fluorometholone acetate 0.1% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1438Q NP	‡1	2	..	13.88	15.05	Flarex [AQ]

▪ FLUOROMETHOLONE ACETATE

Note No applications for increased maximum quantities will be authorised.
Note No applications for increased repeats will be authorised.

fluorometholone acetate 0.1% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5533F OP	‡1	..	..	13.88	15.05	Flarex [AQ]

▪ HYDROCORTISONE ACETATE

hydrocortisone acetate 1% eye ointment, 5 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2441L NP	‡1	..	..	15.87	17.04	Hycor [QA]

▪ HYDROCORTISONE ACETATE

Note No applications for increased maximum quantities will be authorised.
Note No applications for increased repeats will be authorised.

hydrocortisone acetate 1% eye ointment, 5 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5516H OP	‡1	..	..	15.87	17.04	Hycor [QA]

Corticosteroids and mydriatics in combination

▪ PREDNISOLONE ACETATE + PHENYLEPHRINE

Restricted benefit
Corneal grafts
Restricted benefit
Uveitis

prednisolone acetate 1% + phenylephrine hydrochloride 0.12% eye drops, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3112T NP	‡1	2	..	27.29	28.46	Prednefrin Forte [AG]

▪ PREDNISOLONE ACETATE + PHENYLEPHRINE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit
Uveitis

prednisolone acetate 1% + phenylephrine hydrochloride 0.12% eye drops, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5568C OP	‡1	..	..	27.29	28.46	Prednefrin Forte [AG]

ANTIGLAUCOMA PREPARATIONS AND MIOTICS

Sympathomimetics in glaucoma therapy1)

▪ APRACLONIDINE

Restricted benefit
Intra-ocular pressure
Clinical criteria:
The treatment must be for short-term reduction of intra-ocular pressure, AND
Patient must already be on maximally tolerated anti-glaucoma therapy.

apraclonidine 0.5% eye drops, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8083K	‡1	2	..	39.73	38.30	Iopidine 0.5% [AQ]

▪ BRIMONIDINE

brimonidine tartrate 0.15% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5298W	‡1	5	..	22.35	23.52	Alphagan P 1.5 [AG]

brimonidine tartrate 0.2% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8351M	‡1	5	..	22.35	23.52	[a] Enidin [PE]
			[B]1.42	23.77	23.52	[a] Alphagan [AG]

▪ BRIMONIDINE

Note For prescribing in accordance with Optometry Board of Australia guidelines.

brimonidine tartrate 0.15% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5563T OP	‡1	5	..	22.35	23.52	Alphagan P 1.5 [AG]

brimonidine tartrate 0.2% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5534G OP	‡1	5	..	22.35	23.52	[a] Enidin [PE]
			[B]1.42	23.77	23.52	[a] Alphagan [AG]

▪ BRIMONIDINE + TIMOLOL

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

The condition must have been inadequately controlled with monotherapy, AND

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.

brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8826M	‡1	5	..	27.47	28.64	Combigan [AG]

▪ BRIMONIDINE + TIMOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

The condition must have been inadequately controlled with monotherapy, AND

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.

brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5535H (OP)	‡1	5	..	27.47	28.64	Combigan [AG]

Parasympathomimetics

▪ PILOCARPINE

pilocarpine hydrochloride 1% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2595N	‡1	5	..	15.73	16.90	Isopto Carpine [AQ]

pilocarpine hydrochloride 2% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2596P	‡1	5	..	16.82	17.99	Isopto Carpine [AQ]

pilocarpine hydrochloride 4% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2598R	‡1	5	..	19.30	20.47	Isopto Carpine [AQ]

▪ PILOCARPINE

Note For prescribing in accordance with Optometry Board of Australia guidelines.

pilocarpine hydrochloride 1% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5536J (OP)	‡1	5	..	15.73	16.90	Isopto Carpine [AQ]

pilocarpine hydrochloride 2% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5537K (OP)	‡1	5	..	16.82	17.99	Isopto Carpine [AQ]

pilocarpine hydrochloride 4% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5538L (OP)	‡1	5	..	19.30	20.47	Isopto Carpine [AQ]

Carbonic anhydrase inhibitors

▪ ACETAZOLAMIDE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

acetazolamide 250 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1004W (NP)	1	3	..	24.76	25.93	Diamox [RW]

▪ BRINZOLAMIDE

brinzolamide 1% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8483L	‡1	5	..	24.64	25.81	[a] BrinzoQuin [IQ]
			[B]2.28	26.92	25.81	[a] Azopt [AQ]

▪ BRINZOLAMIDE

Note For prescribing in accordance with Optometry Board of Australia guidelines.

brinzolamide 1% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5540N OP	‡1	5	..	24.64	25.81	[a] BrinzoQuin [IQ]
			[B]2.28	26.92	25.81	[a] Azopt [AQ]

▪ BRINZOLAMIDE + BRIMONIDINE

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

The condition must have been inadequately controlled with monotherapy, AND

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.

brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10536M	‡1	5	..	26.98	28.15	Simbrinza 1%/0.2% [AQ]

▪ BRINZOLAMIDE + BRIMONIDINE

Note For prescribing in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

The condition must have been inadequately controlled with monotherapy, AND

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.

brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10547D OP	‡1	5	..	26.98	28.15	Simbrinza 1%/0.2% [AQ]

▪ BRINZOLAMIDE + TIMOLOL

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

The condition must have been inadequately controlled with monotherapy, AND

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.

brinzolamide 1% + timolol 0.5% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3438Y	‡1	5	..	28.21	29.38	Azarga [AQ]

▪ BRINZOLAMIDE + TIMOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

The condition must have been inadequately controlled with monotherapy, AND

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.

brinzolamide 1% + timolol 0.5% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5562R OP	‡1	5	..	28.21	29.38	Azarga [AQ]

▪ DORZOLAMIDE

dorzolamide 2% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8488R	‡1	5	..	21.29	22.46	[a] Trusamide [QA]	[a] Trusopt [MK]

▪ DORZOLAMIDE

Note For prescribing in accordance with Optometry Board of Australia guidelines.

dorzolamide 2% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5541P OP	‡1	5	..	21.29	22.46	[a] Trusamide [QA]	[a] Trusopt [MK]

▪ DORZOLAMIDE + TIMOLOL

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

The condition must have been inadequately controlled with monotherapy, AND

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.

dorzolamide 2% + timolol 0.5% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8567X	‡1	5	..	25.58	26.75	[a] Cosdor [QA] [a] Dorzolamide/Timolol Sandoz 20/5 [SZ]	[a] Cosopt [MK]

▪ DORZOLAMIDE + TIMOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

The condition must have been inadequately controlled with monotherapy, AND

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.

dorzolamide 2% + timolol 0.5% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5542Q OP	‡1	5	..	25.58	26.75	[a] Cosdor [QA] [a] Dorzolamide/Timolol Sandoz 20/5 [SZ]	[a] Cosopt [MK]

Beta blocking agents1)

▪ BETAXOLOL

betaxolol 0.25% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2811Y	‡1	5	..	17.68	18.85	Betoptic S [AQ]

betaxolol 0.5% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2825Q	‡1	5	..	17.68	18.85	[a] BetoQuin [IQ]
			[B]3.08	20.76	18.85	[a] Betoptic [AQ]

▪ BETAXOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

betaxolol 0.25% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5543R OP	‡1	5	..	17.68	18.85	Betoptic S [AQ]

betaxolol 0.5% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5544T OP	‡1	5	..	17.68	18.85	[a] BetoQuin [IQ]
			[B]3.08	20.76	18.85	[a] Betoptic [AQ]

▪ TIMOLOL

timolol 0.1% eye gel, 5 g

8803H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	5	..	16.03	17.20	Nyogel [AS]

timolol 0.25% eye drops, 2.5 mL

1925H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	5	..	14.87	16.04	Timoptol XE [MK]

timolol 0.5% eye drops, 2.5 mL

1926J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	5	..	15.54	16.71	Timoptol XE [MK]

timolol 0.5% eye drops, 5 mL

1279H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	5	..	15.54	16.71	[a] Tenopt [QA]
			[B]2.64	18.18	16.71	[a] Timoptol [FR]

▪ TIMOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

timolol 0.1% eye gel, 5 g

5546X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
OP	‡1	5	..	16.03	17.20	Nyogel [AS]

timolol 0.25% eye drops, 2.5 mL

5549C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
OP	‡1	5	..	14.87	16.04	Timoptol XE [MK]

timolol 0.5% eye drops, 2.5 mL

5550D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
OP	‡1	5	..	15.54	16.71	Timoptol XE [MK]

timolol 0.5% eye drops, 5 mL

5548B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
OP	‡1	5	..	15.54	16.71	[a] Tenopt [QA]
			[B]2.64	18.18	16.71	[a] Timoptol [FR]

Prostaglandin analogues1)

▪ BIMATOPROST

bimatoprost 0.03% eye drops, 3 mL

8620Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	5	..	40.08	38.30	Lumigan [AG]

bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses

10046R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	5	..	35.33	36.50	Lumigan PF [AG]

▪ BIMATOPROST

Note For prescribing in accordance with Optometry Board of Australia guidelines.

bimatoprost 0.03% eye drops, 3 mL

5551E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
OP	‡1	5	..	40.08	38.30	Lumigan [AG]

bimatoprost 0.03% eye drops, 30 x 0.4 mL unit doses

10053D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
OP	‡1	5	..	35.33	36.50	Lumigan PF [AG]

▪ BIMATOPROST + TIMOLOL

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

The condition must have been inadequately controlled with monotherapy, AND

Patient must have open-angle glaucoma; OR
Patient must have ocular hypertension.

bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL unit doses

10107Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	39.06	38.30	GANfort PF 0.3/5 [AG]

▪ BIMATOPROST + TIMOLOL

Restricted benefit
Elevated intra-ocular pressure
Clinical criteria:
The condition must have been inadequately controlled with monotherapy, AND
Patient must have open-angle glaucoma; OR
Patient must have ocular hypertension.

bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL

9464D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	44.54	38.30	Ganfort 0.3/5 [AG]

▪ BIMATOPROST + TIMOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

Restricted benefit
Elevated intra-ocular pressure
Clinical criteria:
The condition must have been inadequately controlled with monotherapy, AND
Patient must have open-angle glaucoma; OR
Patient must have ocular hypertension.

bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL

5558M OP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	44.54	38.30	Ganfort 0.3/5 [AG]

bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL unit doses

10108B OP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	39.06	38.30	GANfort PF 0.3/5 [AG]

▪ LATANOPROST

latanoprost 0.005% eye drops, 2.5 mL

8243W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	5	..	22.86	24.03	[a] APO-Latanoprost [TX] [a] Latanoprost Actavis [EA] [a] Latanoprost Pfizer [FZ] [a] Terry White Chemists Latanoprost [TW] [a] Xalatan [PF]	[a] Chem mart Latanoprost [CH] [a] Latanoprost GH [GQ] [a] Latanoprost Sandoz [SZ] [a] Xalaprost [QA]

▪ LATANOPROST

Note For prescribing in accordance with Optometry Board of Australia guidelines.

latanoprost 0.005% eye drops, 2.5 mL

5552F OP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	5	..	22.86	24.03	[a] APO-Latanoprost [TX] [a] Latanoprost Actavis [EA] [a] Latanoprost Pfizer [FZ] [a] Terry White Chemists Latanoprost [TW] [a] Xalatan [PF]	[a] Chem mart Latanoprost [CH] [a] Latanoprost GH [GQ] [a] Latanoprost Sandoz [SZ] [a] Xalaprost [QA]

▪ LATANOPROST + TIMOLOL

Restricted benefit
Elevated intra-ocular pressure
Clinical criteria:
The condition must have been inadequately controlled with monotherapy, AND
Patient must have open-angle glaucoma; OR
Patient must have ocular hypertension.

latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
8895E	‡1	5	..	27.31	28.48	[a] APO-Latanoprost/Timolol 0.05/5 [TX] [a] Latanoprost/Timolol Sandoz 50/5 [SZ] [a] Xalamol 50/5 [QA]	[a] Latanocom [FZ] [a] Xalacom [PF]

▪ LATANOPROST + TIMOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

The condition must have been inadequately controlled with monotherapy, AND

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.

latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5553G OP	‡1	5	..	27.31	28.48	[a] APO-Latanoprost/Timolol 0.05/5 [TX] [a] Latanoprost/Timolol Sandoz 50/5 [SZ] [a] Xalamol 50/5 [QA]	[a] Latanocom [FZ] [a] Xalacom [PF]

▪ TAFLUPROST

tafluprost 0.0015% eye drops, 30 x 0.3 mL unit doses

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2755B	‡1	5	..	34.25	35.42	Saflutan [MK]

▪ TAFLUPROST

Note For prescribing in accordance with Optometry Board of Australia guidelines.

tafluprost 0.0015% eye drops, 30 x 0.3 mL unit doses

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2748P OP	‡1	5	..	34.25	35.42	Saflutan [MK]

▪ TRAVOPROST

travoprost 0.004% eye drops, 2.5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8597L	‡1	5	..	40.08	38.30	Travatan [AQ]

▪ TRAVOPROST

Note For prescribing in accordance with Optometry Board of Australia guidelines.

travoprost 0.004% eye drops, 2.5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5554H OP	‡1	5	..	40.08	38.30	Travatan [AQ]

▪ TRAVOPROST + TIMOLOL

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

The condition must have been inadequately controlled with monotherapy, AND

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.

travoprost 0.004% + timolol 0.5% eye drops, 2.5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9057Q	‡1	5	..	44.54	38.30	Duotrav [AQ]

▪ TRAVOPROST + TIMOLOL

Note For prescribing in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:
The condition must have been inadequately controlled with monotherapy, AND
Patient must have open-angle glaucoma; OR
Patient must have ocular hypertension.

travoprost 0.004% + timolol 0.5% eye drops, 2.5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5555J OP	‡1	5	..	44.54	38.30	Duotrav [AQ]

MYDRIATICS AND CYCLOPLEGICS

Anticholinergics

▪ ATROPINE SULFATE

ATROPINE Eye drops containing atropine sulfate 10 mg per mL (1%), 15 mL, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1093M NP	‡1	2	..	23.11	24.28	Atropt [QA]

▪ HOMATROPINE

homatropine hydrobromide 2% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10063P OP	‡1	2	..	20.66	21.83	Isopto Homatropine [AQ]

homatropine hydrobromide 2% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2541R NP	‡1	2	..	20.66	21.83	Isopto Homatropine [AQ]

DECONGESTANTS AND ANTIALLERGICS

Other antiallergics

▪ CROMOGLYCATE

Restricted benefit
Vernal kerato-conjunctivitis

cromoglycate sodium 2% eye drops, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1127H NP	‡1	5	..	15.86	17.03	Opticrom [SW]

cromoglycate sodium 2% eye drops, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5529B OP	‡1	5	..	15.86	17.03	Opticrom [SW]

OCULAR VASCULAR DISORDER AGENTS

Antineovascularisation agents

▪ AFLIBERCEPT

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Diabetic macular oedema (DMO)
Treatment Phase: Initial treatment
Clinical criteria:
Patient must have visual impairment due to diabetic macular oedema, AND
Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, AND
The condition must be diagnosed by fluorescein angiography; OR
The condition must be diagnosed by fluorescein angiography; OR
Patient must have a contraindication to fluorescein angiography; OR
Patient must have a contraindication to fluorescein angiography, AND
The treatment must be as monotherapy; OR
The treatment must be in combination with laser photocoagulation, AND
The treatment must be the sole PBS-subsidised therapy for this condition.
Treatment criteria:
Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

a) a completed authority prescription form;

b) a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and

c) a copy of the fluorescein angiogram or alternative method of diagnosis where applicable.

A telephone application must be made following submission by facsimile of a copy of a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form and a copy of the fluorescein angiogram report. The original documentation must be submitted to the Chief Executive Medicare by post after the application has been authorised.

Where a fluorescein angiogram cannot be performed due to a contraindication as listed in the TGA-approved product information, details of the contraindication must be provided. A copy of the report of an alternative method of diagnosis must be included in the application, for example optical coherence tomography or red free photography.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Authority required

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug for the same eye, AND

The treatment must be as monotherapy; OR

The treatment must be in combination with laser photocoagulation, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

Must be treated by an ophthalmologist.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

aflibercept 4 mg/0.1 mL injection, 1 x 0.1 mL vial

10505X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1148.77	38.30	Eylea [BN]

▪ AFLIBERCEPT

Note Special Pricing Arrangements apply.

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be due to age-related macular degeneration (AMD), AND

The condition must be diagnosed by fluorescein angiography, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

a) a completed authority prescription form;

b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and

c) a copy of the fluorescein angiogram.

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the fluorescein angiogram. The original documentation must be submitted to the Chief Executive Medicare by post after the application has been authorised.

Where a fluorescein angiogram cannot be performed due to a contraindication as listed in the TGA-approved product information, details of the contraindication must be provided. A copy of the report of an alternative method of diagnosis must be included in the application, for example, optical coherence tomography (OCT) or red free photography.

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Note Authority approvals will be administered by the Complex Drugs Unit of the Department of Human Services.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must be due to age-related macular degeneration (AMD), AND

The treatment must be the sole PBS-subsidised therapy for this condition, AND

Patient must have previously been granted an authority prescription for the same eye.

Treatment criteria:

Must be treated by an ophthalmologist.

Note Authority approvals will be administered by the Complex Drugs Unit of the Department of Human Services.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum number of repeats may be authorised.

Authority required

Central retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), AND

Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, AND

The condition must be diagnosed by fluorescein angiography; OR

The condition must be diagnosed by fluorescein angiography; OR

Patient must have a contraindication to fluorescein angiography; OR

Patient must have a contraindication to fluorescein angiography, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

a) a completed authority prescription form;

b) a completed Central Retinal Vein Occlusion (CRVO) - PBS Supporting Information Form; and

c) a copy of the fluorescein angiogram or alternative method of diagnosis where applicable.

A telephone application must be made following submission by facsimile of a copy of a completed Central Retinal Vein Occlusion (CRVO) - PBS Supporting Information Form and a copy of the fluorescein angiogram report. The original documentation must be submitted to the Chief Executive Medicare by post after the application has been authorised.

Where a fluorescein angiogram cannot be performed due to a contraindication as listed in the TGA-approved product information, details of the contraindication must be provided. A copy of the report of an alternative method of diagnosis must be included in the application, for example optical coherence tomography or red free photography.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug for the same eye, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

Must be treated by an ophthalmologist.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

aflibercept 4 mg/0.1 mL injection, 1 x 0.1 mL vial

2168D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	1148.77	38.30	Eylea [BN]

▪ RANIBIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

Authority required

Diabetic macular oedema (DMO)

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have visual impairment due to diabetic macular oedema, AND

Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment, AND

The condition must be diagnosed by fluorescein angiography; OR

The condition must be diagnosed by fluorescein angiography; OR

Patient must have a contraindication to fluorescein angiography; OR

Patient must have a contraindication to fluorescein angiography, AND

The treatment must be as monotherapy; OR

The treatment must be in combination with laser photocoagulation, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

a) a completed authority prescription form;

b) a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form; and

c) a copy of the fluorescein angiogram or alternative method of diagnosis where applicable.

A telephone application must be made following submission by facsimile of a copy of a completed Diabetic Macular Oedema (DMO) - PBS Supporting Information Form and a copy of the fluorescein angiogram report. The original documentation must be submitted to the Chief Executive Medicare by post after the application has been authorised.

Where a fluorescein angiogram cannot be performed due to a contraindication as listed in the TGA-approved product information, details of the contraindication must be provided. A copy of the report of an alternative method of diagnosis must be included in the application, for example optical coherence tomography or red free photography.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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Authority required

Diabetic macular oedema (DMO)

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug for the same eye, AND

The treatment must be as monotherapy; OR

The treatment must be in combination with laser photocoagulation, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

Must be treated by an ophthalmologist.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

ranibizumab 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe

10374B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1148.77	38.30	[a] Lucentis [NV]

ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial

10373Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1148.77	38.30	[a] Lucentis [NV]

▪ RANIBIZUMAB

Note Special Pricing Arrangements apply.

Note Pharmaceutical benefits that have the form ranibizumab 0.165 mL injection syringe and pharmaceutical benefits that have the form ranibizumab 0.23 mL injection vial are equivalent for the purposes of substitution.

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be due to age-related macular degeneration (AMD), AND

The condition must be diagnosed by fluorescein angiography, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

Must be treated by an ophthalmologist.

Authority approval for initial treatment of each eye must be sought.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

a) a completed authority prescription form;

b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and

c) a copy of the fluorescein angiogram.

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the fluorescein angiogram. The original documentation must be submitted to the Chief Executive Medicare by post after the application has been authorised.

Where a fluorescein angiogram cannot be performed due to a contraindication as listed in the TGA-approved product information, details of the contraindication must be provided. A copy of the report of an alternative method of diagnosis must be included in the application, for example, optical coherence tomography (OCT) or red free photography.

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must be due to age-related macular degeneration (AMD), AND

The treatment must be the sole PBS-subsidised therapy for this condition, AND

Patient must have previously been granted an authority prescription for the same eye.

Treatment criteria:

Must be treated by an ophthalmologist.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Branch retinal vein occlusion with macular oedema

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), AND

Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment, AND

The condition must be diagnosed by fluorescein angiography; OR
The condition must be diagnosed by fluorescein angiography; OR
Patient must have a contraindication to fluorescein angiography; OR
Patient must have a contraindication to fluorescein angiography, AND
The treatment must be the sole PBS-subsidised therapy for this condition.
Treatment criteria:
Must be treated by an ophthalmologist.
Authority approval for initial treatment of each eye must be sought.
The first authority application for each eye must be made in writing or by telephone.
A written application must include:
a) a completed authority prescription form;
b) a completed Branched Retinal Vein Occlusion (BRVO) - PBS Supporting Information Form; and
c) a copy of the fluorescein angiogram or alternative method of diagnosis where applicable.
A telephone application must be made following submission by facsimile of a copy of a completed Branched Retinal Vein Occlusion (BRVO) - PBS Supporting Information Form and a copy of the fluorescein angiogram report. The original documentation must be submitted to the Chief Executive Medicare by post after the application has been authorised.
Where a fluorescein angiogram cannot be performed due to a contraindication as listed in the TGA-approved product information, details of the contraindication must be provided. A copy of the report of an alternative method of diagnosis must be included in the application, for example optical coherence tomography or red free photography.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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Applications for authority to prescribe should be forwarded to:
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Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Branch retinal vein occlusion with macular oedema
Treatment Phase: Continuing treatment
Clinical criteria:
Patient must have previously been issued with an authority prescription for this drug for the same eye, AND
The treatment must be the sole PBS-subsidised therapy for this condition.
Treatment criteria:
Must be treated by an ophthalmologist.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Central retinal vein occlusion with macular oedema
Treatment Phase: Initial treatment
Clinical criteria:
Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), AND
Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment, AND
The condition must be diagnosed by fluorescein angiography; OR
The condition must be diagnosed by fluorescein angiography; OR
Patient must have a contraindication to fluorescein angiography; OR
Patient must have a contraindication to fluorescein angiography, AND
The treatment must be the sole PBS-subsidised therapy for this condition.
Treatment criteria:
Must be treated by an ophthalmologist.
Authority approval for initial treatment of each eye must be sought.
The first authority application for each eye must be made in writing or by telephone.
A written application must include:
a) a completed authority prescription form;
b) a completed Central Retinal Vein Occlusion (CRVO) - PBS Supporting Information Form; and
c) a copy of the fluorescein angiogram or alternative method of diagnosis where applicable.

A telephone application must be made following submission by facsimile of a copy of a completed Central Retinal Vein Occlusion (CRVO) - PBS Supporting Information Form and a copy of the fluorescein angiogram report. The original documentation must be submitted to the Chief Executive Medicare by post after the application has been authorised.

Where a fluorescein angiogram cannot be performed due to a contraindication as listed in the TGA-approved product information, details of the contraindication must be provided. A copy of the report of an alternative method of diagnosis must be included in the application, for example optical coherence tomography or red free photography.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
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Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Central retinal vein occlusion with macular oedema

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug for the same eye, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

Must be treated by an ophthalmologist.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

ranibizumab 1.65 mg/0.165 mL injection, 1 x 0.165 mL syringe

10138N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	1148.77	38.30	[a] Lucentis [NV]

ranibizumab 2.3 mg/0.23 mL injection, 0.23 mL vial

1382R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	1148.77	38.30	[a] Lucentis [NV]

▪ VERTEPORFIN

Note The Department of Human Services should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum.

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be predominantly classic (greater than or equal to 50%), AND

The treatment must be the sole PBS-subsidised therapy for this condition, AND

The condition must be due to age-related macular degeneration (AMD), AND

The condition must be diagnosed by fluorescein angiography, AND

Patient must have a baseline visual acuity equal to or better than 6/60 (20/200).

Treatment criteria:

Must be treated by an ophthalmologist.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

a) a completed authority prescription form;

b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form; and

c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the fluorescein angiogram. The original documentation must be submitted to the Chief Executive Medicare by post after the application has been authorised.

Note Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Note The original documentation must be posted to the above address after approval has been gained.

Note No more than 15 treatments (1 initial and 14 continuing) per eye will be authorised.

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Initial PBS-subsidised treatment

Clinical criteria:

The condition must be predominantly classic (greater than or equal to 50%), AND

The condition must be due to macular degeneration, AND

Patient must have been authorised by the Angiogram Review Panel to receive treatment with verteporfin in the same eye under the MBS Visudyne Therapy Program, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

Must be treated by a ophthalmologist.

The first authority application for each eye must be made in writing or by telephone.

A written application must include:

(a) a completed authority prescription form; and

(b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form, which includes the date of review by the Angiogram Review Panel and the number of treatments administered in that eye under the MBS Visudyne Therapy Program; and

(c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).

A telephone application must be made following submission by facsimile of a copy of a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form and a copy of the fluorescein angiogram. The original documentation must be submitted to the Chief Executive Medicare by post after the application has been authorised.

Note Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note The first authority application may be faxed to the Department of Human Services on 1300 093 177 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The Department will then contact the prescriber by telephone.

Note The original documentation must be posted to the above address after approval has been gained.

Note A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS.

Authority required

Subfoveal choroidal neovascularisation (CNV)

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must be predominantly classic (greater than or equal to 50%), AND

The condition must be due to macular degeneration, AND

The treatment must be the sole PBS-subsidised therapy for this condition, AND

Patient must have previously been granted an authority prescription for the same eye.

Treatment criteria:

Must be treated by an ophthalmologist.

Note A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS.

Note Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

verteporfin 15 mg injection, 1 vial

1349B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	2141.33	38.30	Visudyne [NV]

OTHER OPHTHALMOLOGICALS

Other ophthalmologicals

▪ CARBOMER-974

Authority required (STREAMLINED)

6172

Severe dry eye syndrome

Clinical criteria:

Patient must be sensitive to preservatives in multi-dose eye drops.

carbomer-974 0.3% eye gel, 30 x 500 mg unit doses

5502N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
OP	3	5	..	*34.89	36.06	Poly Gel [AQ]

carbomer-974 0.3% eye gel, 30 x 500 mg unit doses

8514D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	3	5	..	*34.89	36.06	Poly Gel [AQ]

▪ CARBOMER-980

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

carbomer-980 0.2% eye gel, 10 g

5503P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	‡1	5	..	13.24	14.41	[a] Optifresh eye gel [PP]	[a] PAA [IQ]
			[B]3.85	17.09	14.41	[a] Viscotears [AQ]	

carbomer-980 0.2% eye gel, 10 g

8384G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	5	..	13.24	14.41	[a] Optifresh eye gel [PP]	[a] PAA [IQ]
			[B]3.85	17.09	14.41	[a] Viscotears [AQ]	

▪ CARBOMER-980

Authority required (STREAMLINED)

6172

Severe dry eye syndrome

Clinical criteria:

Patient must be sensitive to preservatives in multi-dose eye drops.

carbomer-980 0.2% eye drops, 30 x 0.6 mL unit doses

5504Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
OP	3	5	..	*36.21	37.38	Viscotears Gel PF [AQ]

carbomer-980 0.2% eye drops, 30 x 0.6 mL unit doses

8578L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	3	5	..	*36.21	37.38	Viscotears Gel PF [AQ]

▪ CARBOMER-980

Note No applications for increased maximum quantities will be authorised.

Note No applications for repeats will be authorised.

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

Clinical criteria:

Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

carbomer-980 0.2% eye gel, 10 g

9210R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	11	..	13.24	14.41	[a] Optifresh eye gel [PP]	[a] PAA [IQ]
			[B]3.85	17.09	14.41	[a] Viscotears [AQ]	

▪ CARMELLOSE SODIUM

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

carmellose sodium 1% (10 mg/mL) eye drops, 15 mL

5508X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
OP	‡1	5	..	13.87	15.04	Refresh Liquigel [AG]

carmellose sodium 0.5% (5 mg/mL) eye drops, 15 mL

5507W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
OP	‡1	5	..	13.87	15.04	Refresh Tears Plus [AG]

▪ CARMELLOSE SODIUM

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

carmellose sodium 1% (10 mg/mL) eye drops, 15 mL

8593G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	13.87	15.04	Refresh Liquigel [AG]

carmellose sodium 0.5% (5 mg/mL) eye drops, 15 mL

8548X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	13.87	15.04	Refresh Tears Plus [AG]

▪ CARMELLOSE SODIUM

Authority required (STREAMLINED)

6172

Severe dry eye syndrome

Clinical criteria:

Patient must be sensitive to preservatives in multi-dose eye drops.

carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses

2324H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	3	5	..	*30.96	32.13	[a] Optifresh Plus [PP]
			[B]7.29	*38.25	32.13	[a] Celluvisc [AG]

carmellose sodium 1% (4 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses

5505R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
OP	3	5	..	*30.96	32.13	[a] Optifresh Plus [PP]
			[B]7.29	*38.25	32.13	[a] Celluvisc [AG]

carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses

5509Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
OP	4	5	..	*38.49	38.30	TheraTears [CX]

carmellose sodium 0.25% (1.5 mg/0.6 mL) eye drops, 24 x 0.6 mL unit doses

8823J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	4	5	..	*38.49	38.30	TheraTears [CX]

carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses

2338C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	3	5	..	*30.96	32.13	[a] Optifresh Tears [PP]
			[B]7.29	*38.25	32.13	[a] Cellufresh [AG]

carmellose sodium 0.5% (2 mg/0.4 mL) eye drops, 30 x 0.4 mL unit doses

5506T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
OP	3	5	..	*30.96	32.13	[a] Optifresh Tears [PP]
			[B]7.29	*38.25	32.13	[a] Cellufresh [AG]

carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses

5510B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
OP	3	5	..	*33.27	34.44	TheraTears [CX]

carmellose sodium 1% (6 mg/0.6 mL) eye gel, 28 x 0.6 mL unit doses

8824K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	3	5	..	*33.27	34.44	TheraTears [CX]

▪ CARMELLOSE SODIUM

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

Clinical criteria:

Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

carmellose sodium 1% (10 mg/mL) eye drops, 15 mL

9212W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	11	..	13.87	15.04	Refresh Liquigel [AG]

carmellose sodium 0.5% (5 mg/mL) eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9211T	‡1	11	..	13.87	15.04	Refresh Tears Plus [AG]

▪ CARMELLOSE SODIUM + GLYCEROL

Note The in-use shelf life of Optive is 6 months from the date of opening.

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5556K OP	‡1	3	..	13.87	15.04	Optive [AG]

▪ CARMELLOSE SODIUM + GLYCEROL

Note The in-use shelf life of Optive is 6 months from the date of opening.

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9355J NP	‡1	3	..	13.87	15.04	Optive [AG]

▪ CARMELLOSE SODIUM + GLYCEROL

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note The in-use shelf life of Optive is 6 months from the date of opening.

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

Clinical criteria:

Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9356K	‡1	7	..	13.87	15.04	Optive [AG]

▪ DEXTRAN-70 + HYPROMELLOSE

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1509K NP	‡1	5	..	13.96	15.13	[a] Poly-Tears [IQ]
			[B]3.65	17.61	15.13	[a] Tears Naturale [AQ]

▪ DEXTRAN-70 + HYPROMELLOSE

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5520M OP	‡1	5	..	13.96	15.13	[a] Poly-Tears [IQ]
			[B]3.65	17.61	15.13	[a] Tears Naturale [AQ]

▪ DEXTRAN-70 + HYPROMELLOSE

Authority required (STREAMLINED)

6172

Severe dry eye syndrome

Clinical criteria:

Patient must be sensitive to preservatives in multi-dose eye drops.

dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5521N OP	3	5	..	*35.31	36.48	Bion Tears [AQ]

dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL unit doses

8299T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	3	5	..	*35.31	36.48	Bion Tears [AQ]

▪ DEXTRAN-70 + HYPROMELLOSE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit
Severe dry eye syndrome, including Sjogren's syndrome
Clinical criteria:
Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL

9216C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	11	..	13.96	15.13	[a] Poly-Tears [IQ]
			[B]3.65	17.61	15.13	[a] Tears Naturale [AQ]

▪ HYPROMELLOSE

Restricted benefit
Severe dry eye syndrome, including Sjogren's syndrome

HYPROMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1

8287E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	13.77	14.94	[a] In a Wink Moisturising [IQ]
			[B]2.88	16.65	14.94	[a] Genteal [AQ]

HYPROMELLOSE Eye drops 5 mg per mL (0.5%), 15 mL, 1

2956N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	13.77	14.94	Methopt [QA]

▪ HYPROMELLOSE

Restricted benefit
Severe dry eye syndrome, including Sjogren's syndrome

HYPROMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1

5518K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
OP	‡1	5	..	13.77	14.94	[a] In a Wink Moisturising [IQ]
			[B]2.88	16.65	14.94	[a] Genteal [AQ]

HYPROMELLOSE Eye drops 5 mg per mL (0.5%), 15 mL, 1

5517J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
OP	‡1	5	..	13.77	14.94	Methopt [QA]

▪ HYPROMELLOSE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit
Severe dry eye syndrome, including Sjogren's syndrome
Clinical criteria:
Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

HYPROMELLOSE Eye drops 3 mg per mL (0.3%), 15 mL (contains sodium perborate as preservative), 1

9213X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	11	..	13.77	14.94	[a] In a Wink Moisturising [IQ]
			[B]2.88	16.65	14.94	[a] Genteal [AQ]

HYPROMELLOSE Eye drops 5 mg per mL (0.5%), 15 mL, 1

9214Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	11	..	13.77	14.94	Methopt [QA]

▪ HYPROMELLOSE + CARBOMER-980

Restricted benefit
Severe dry eye syndrome, including Sjogren's syndrome

hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5519L OP	‡1	5	..	13.77	14.94	[a] HPMC PAA [IQ]
			[B]2.88	16.65	14.94	[a] Genteal gel [AQ]

▪ HYPROMELLOSE + CARBOMER-980

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8564R NP	‡1	5	..	13.77	14.94	[a] HPMC PAA [IQ]
			[B]2.88	16.65	14.94	[a] Genteal gel [AQ]

▪ HYPROMELLOSE + CARBOMER-980

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

Clinical criteria:

Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9215B	‡1	11	..	13.77	14.94	[a] HPMC PAA [IQ]
			[B]2.88	16.65	14.94	[a] Genteal gel [AQ]

▪ PARAFFIN

paraffin 1 g/g eye ointment, 2 x 3.5 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1750D NP	‡1	5	..	22.75	23.92	Poly Visc [IQ] [a] Ircal [PE]
			[B]1.84	24.59	23.92	[a] Refresh Night Time [AG]

paraffin 1 g/g eye ointment, 2 x 3.5 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5522P OP	‡1	5	..	22.75	23.92	Poly Visc [IQ] [a] Ircal [PE]
			[B]1.84	24.59	23.92	[a] Refresh Night Time [AG]

paraffin 1 g/g eye ointment, 3.5 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1754H NP	2	5	..	*23.31	24.48	Poly Visc [IQ]

paraffin 1 g/g eye ointment, 3.5 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5523Q OP	2	5	..	*23.31	24.48	Poly Visc [IQ]

▪ PARAFFIN

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

paraffin 1 g/g eye ointment, 2 x 3.5 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9218E	‡1	11	..	22.75	23.92	Poly Visc [IQ] [a] Ircal [PE]
			[B]1.84	24.59	23.92	[a] Refresh Night Time [AG]

▪ PARAFFIN

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

paraffin 1 g/g eye ointment, 3.5 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9217D	2	11	..	*23.31	24.48	Poly Visc [IQ]

▪ PARAFFIN

Note The in-use shelf life of VitA-POS is 6 months from the date of opening.

paraffin + retinyl palmitate 0.0138% eye ointment, 5 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2167C OP	2	5	..	*23.31	24.48	VitA-POS [AE]

paraffin + retinyl palmitate 0.0138% eye ointment, 5 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2222Y NP	2	5	..	*23.31	24.48	VitA-POS [AE]

▪ PARAFFIN

Note The in-use shelf life of VitA-POS is 6 months from the date of opening.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

paraffin + retinyl palmitate 0.0138% eye ointment, 5 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2202X	2	11	..	*23.31	24.48	VitA-POS [AE]

▪ POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5524R OP	‡1	5	..	13.87	15.04	Systane [AQ]

▪ POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8676P NP	‡1	5	..	13.87	15.04	Systane [AQ]

▪ POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

Authority required (STREAMLINED)

6172

Severe dry eye syndrome

Clinical criteria:

Patient must be sensitive to preservatives in multi-dose eye drops.

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5532E OP	2	5	..	*33.29	34.46	Systane [AQ]

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9170P NP	2	5	..	*33.29	34.46	Systane [AQ]

▪ POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

Clinical criteria:

Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9219F	‡1	11	..	13.87	15.04	Systane [AQ]

▪ POLYVINYL ALCOHOL

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

polyvinyl alcohol 1.4% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2682E NP	‡1	5	..	13.77	14.94	[a] PVA Tears [PE]
			[B]1.39	15.16	14.94	[a] Liquifilm Tears [AG]

polyvinyl alcohol 1.4% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8831T NP	‡1	5	..	13.77	14.94	Vistil [AE]

polyvinyl alcohol 3% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8832W NP	‡1	5	..	13.77	14.94	Vistil Forte [AE]

▪ POLYVINYL ALCOHOL

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

polyvinyl alcohol 1.4% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5526W OP	‡1	5	..	13.77	14.94	[a] PVA Tears [PE]
			[B]1.39	15.16	14.94	[a] Liquifilm Tears [AG]

polyvinyl alcohol 1.4% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5527X OP	‡1	5	..	13.77	14.94	Vistil [AE]

polyvinyl alcohol 3% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5528Y OP	‡1	5	..	13.77	14.94	Vistil Forte [AE]

▪ POLYVINYL ALCOHOL

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

Clinical criteria:

Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

polyvinyl alcohol 1.4% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9220G	‡1	11	..	13.77	14.94	[a] PVA Tears [PE]
			[B]1.39	15.16	14.94	[a] Liquifilm Tears [AG]

polyvinyl alcohol 1.4% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9221H	‡1	11	..	13.77	14.94	Vistil [AE]

polyvinyl alcohol 3% eye drops, 15 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9223K	‡1	11	..	13.77	14.94	Vistil Forte [AE]

▪ SODIUM HYALURONATE

Note The in-use shelf life of Hylo-Fresh and Hylo-Forte is 6 months from the date of opening.

Authority required (STREAMLINED)

4105

Severe dry eye syndrome
Clinical criteria:
Patient must be sensitive to preservatives in multi-dose eye drops.

sodium hyaluronate 0.1% (1 mg/mL) eye drops, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2181T NP	‡1	5	..	34.07	35.24	Hylo-Fresh [AE]

sodium hyaluronate 0.1% (1 mg/mL) eye drops, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2184Y OP	‡1	5	..	34.07	35.24	Hylo-Fresh [AE]

sodium hyaluronate 0.2% (2 mg/mL) eye drops, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2171G OP	‡1	5	..	34.07	35.24	Hylo-Forte [AE]

sodium hyaluronate 0.2% (2 mg/mL) eye drops, 10 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2253N NP	‡1	5	..	34.07	35.24	Hylo-Forte [AE]

▪ SOY LECITHIN + TOCOPHEROLS + VITAMIN A

Authority required (STREAMLINED)
6172
Severe dry eye syndrome
Clinical criteria:
Patient must be sensitive to preservatives in multi-dose eye drops.

soy lecithin 1% + tocopherols 0.002% + vitamin A palmitate 0.025% eye spray, 100 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5545W OP	2	5	..	*34.93	36.10	tearsagain [RB]

soy lecithin 1% + tocopherols 0.002% + vitamin A palmitate 0.025% eye spray, 100 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9448G NP	2	5	..	*34.93	36.10	tearsagain [RB]

▪ OTOLOGICALS

ANTIINFECTIVES

Antiinfectives

▪ CIPROFLOXACIN

Authority required
Chronic suppurative otitis media
Population criteria:
Patient must be an Aboriginal or a Torres Strait Islander person, AND
Patient must be aged 1 month or older.
Authority required
Chronic suppurative otitis media
Clinical criteria:
Patient must have perforation of the tympanic membrane.
Population criteria:
Patient must be less than 18 years of age.
Authority required
Chronic suppurative otitis media
Clinical criteria:
Patient must have a grommet in situ.
Population criteria:
Patient must be less than 18 years of age.

ciprofloxacin 0.3% ear drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2480M NP	‡1	1	..	21.60	22.77	Ciloxan [AQ]

CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION

Corticosteroids and antiinfectives in combination

▪ FRAMYCETIN SULFATE + GRAMICIDIN + DEXAMETHASONE

framycetin sulfate 0.5% + gramicidin 0.005% + dexamethasone 0.05% ear drops, 8 mL

2781J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	2	..	13.48	14.65	[a] Otodex [AV]
			[B]1.66	15.14	14.65	[a] Sofradex [SW]

▪ TRIAMCINOLONE + NEOMYCIN SULFATE + GRAMICIDIN + NYSTATIN

triamcinolone acetonide 0.1% + neomycin sulfate 0.25% + gramicidin 0.025% + nystatin 100 000 international units/g ointment, 5 g

2974M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	2	..	11.95	13.12	[a] Otocomb Otic [FM]
			[B]1.70	13.65	13.12	[a] Kenacomb Otic [QA]

triamcinolone acetonide 0.1% + neomycin sulfate 0.25% + gramicidin 0.025% + nystatin 100 000 international units/mL ear drops, 7.5 mL

2971J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	2	..	14.48	15.65	[a] Otocomb Otic [FM]
			[B]1.70	16.18	15.65	[a] Kenacomb Otic [QA]

▪ OPHTHALMOLOGICAL AND OTOLOGICAL PREPARATIONS

ANTIINFECTIVES

Antiinfectives

▪ FRAMYCETIN SULFATE

framycetin sulfate 0.5% eye/ear drops, 8 mL

1440T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP MW	‡1	2	..	14.00	15.17	Soframycin [SW]

framycetin sulfate 0.5% eye/ear drops, 8 mL

5557L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
OP	‡1	2	..	14.00	15.17	Soframycin [SW]

▪ VARIOUS

▪ ALLERGENS

ALLERGENS

Allergen extracts

▪ BEE VENOM

bee venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack

2886X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	263.84	38.30	Albey Bee Venom [DE]

bee venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 1 pack

10621B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	263.84	38.30	Hymenoptera Honey Bee Venom [DE]

▪ PAPER WASP VENOM

Note Paper wasp venom is not European wasp venom

paper wasp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack

2918N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	263.84	38.30	Albey Paper Wasp Venom [DE]

paper wasp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 1 pack

10620Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	263.84	38.30	Hymenoptera Paper Wasp Venom [DE]

▪ VESPULA SPP VENOM

vespula spp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial] (&) inert substance diluent [3 x 1.8 mL vials], 1 pack

2883R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	263.84	38.30	Albey Yellow Jacket Venom [DE]

vespula spp venom 550 microgram injection [1 vial] (&) inert substance diluent [9 mL vial], 1 pack

10622C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	263.84	38.30	Hymenoptera Yellow Jacket Venom [DE]

▪ ALL OTHER THERAPEUTIC PRODUCTS

ALL OTHER THERAPEUTIC PRODUCTS

Antidotes

▪ NALOXONE

naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules

10783M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	95.41	38.30	Naloxone Hydrochloride (DBL) [HH]

naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules

10787R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
DP	1	..	..	95.41	38.30	Naloxone Hydrochloride (DBL) [HH]

Drugs for treatment of hyperkalemia and hyperphosphatemia

▪ LANTHANUM

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
5491
Hyperphosphataemia
Treatment Phase: Maintenance following initiation and stabilisation
Clinical criteria:
The condition must not be adequately controlled by calcium, AND
Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND
The treatment must not be used in combination with any other non-calcium phosphate binding agents.
Treatment criteria:
Patient must be undergoing dialysis for chronic kidney disease.

LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90

9405B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	474.58	38.30	Fosrenol [ZI]

LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90

9403X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	280.86	38.30	Fosrenol [ZI]

LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90

9404Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	422.01	38.30	Fosrenol [ZI]

▪ SEVELAMER

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
5491

Hyperphosphataemia
Treatment Phase: Maintenance following initiation and stabilisation
Clinical criteria:
The condition must not be adequately controlled by calcium, AND
Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND
The treatment must not be used in combination with any other non-calcium phosphate binding agents.
Treatment criteria:
Patient must be undergoing dialysis for chronic kidney disease.

sevelamer hydrochloride 800 mg tablet, 180

2142R (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	331.85	38.30	Renagel [GZ]

▪ SUCROFERRIC OXYHYDROXIDE

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)
5491
Hyperphosphataemia
Treatment Phase: Maintenance following initiation and stabilisation
Clinical criteria:
The condition must not be adequately controlled by calcium, AND
Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND
The treatment must not be used in combination with any other non-calcium phosphate binding agents.
Treatment criteria:
Patient must be undergoing dialysis for chronic kidney disease.

iron (as sucroferric oxyhydroxide) 500 mg tablet: chewable, 90

10250L (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	423.36	38.30	Velphoro [FN]

Detoxifying agents for antineoplastic treatment

▪ FOLINIC ACID

folinic acid 1 g/100 mL injection, 100 mL vial

8969C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	49.11	38.30	Calcium Folinate Ebewe [SZ]

folinic acid 300 mg/30 mL injection, 30 mL vial

9041W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	1	..	*55.69	38.30	[a] Calcium Folinate Ebewe [SZ]	[a] Leucovorin Calcium (Hospira Pty Limited) [HH]

▪ FOLINIC ACID

Note For item codes 8740B and 1610R, pharmaceutical benefits that have the form injection equivalent to 50 mg folinic acid in 5 mL are equivalent for the purposes of substitution.

folinic acid 50 mg/5 mL injection, 10 x 5 mL ampoules

1610R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	52.25	38.30	[a] Leucovorin Calcium (Pfizer Australia Pty Ltd) [PF]

folinic acid 50 mg/5 mL injection, 5 mL vial

8740B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10	2	..	*52.23	38.30	[a] Leucovorin Calcium (Hospira Pty Limited) [HH]

▪ FOLINIC ACID

Note For item codes 8812T and 1704Q, pharmaceutical benefits that have the form injection equivalent to 100 mg folinic acid in 10 mL are equivalent for the purposes of substitution.

folinic acid 100 mg/10 mL injection, 10 mL vial

8812T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	10	1	..	*57.53	38.30	[a] Calcium Folinate Ebewe [SZ]

folinic acid 100 mg/10 mL injection, 10 x 10 mL ampoules

1704Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	57.51	38.30	[a] Leucovorin Calcium (Pfizer Australia Pty Ltd) [PF]

▪ FOLINIC ACID

Restricted benefit

Megaloblastic anaemias

Clinical criteria:

The condition must be a result of folic acid deficiency from the use of folic acid antagonists.

folinic acid 15 mg tablet, 10

2308L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	92.14	38.30	Leucovorin Calcium (Hospira Pty Limited) [HH]

▪ MESNA

Restricted benefit

Urothelial toxicity

Treatment Phase: Prophylaxis or reduction of toxicity

Clinical criteria:

The treatment must be adjunctive therapy to ifosfamide or high dose cyclophosphamide.

mesna 1 g/10 mL injection, 15 x 10 mL ampoules

8079F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	200.17	38.30	Uromitexan [BX]

mesna 400 mg/4 mL injection, 15 x 4 mL ampoules

8078E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	94.07	38.30	Uromitexan [BX]

Drugs for treatment of hypercalcemia

▪ PHOSPHORUS

Authority required (STREAMLINED)

5089

Hypophosphataemic rickets

Authority required (STREAMLINED)

5114

Vitamin D-resistant rickets

Authority required (STREAMLINED)

5095

Familial hypophosphataemia

Authority required (STREAMLINED)

5123

Hypercalcaemia

phosphorus 500 mg tablet: effervescent, 100

2946C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	..	75.37	38.30	Phosphate Sandoz [NV]

Other therapeutic products

▪ POLYLACTIC ACID

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Authority applications may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe facial lipoatrophy

Treatment Phase: Initial PBS-subsidised treatment

Clinical criteria:

The treatment must be for facial administration only, AND

The condition must be caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Galderma is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.

polylactic acid 150 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9475Q	2	4	..	*419.09	38.30	Sculptra [GA]

▪ POLYLACTIC ACID

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Maintenance treatment is limited to one re-treatment (maximum 2 vials) every 2 years.
Note Authority applications may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe facial lipoatrophy

Treatment Phase: Maintenance PBS-subsidised treatment

Clinical criteria:

The treatment must be for facial administration only, AND

The condition must be caused by therapy for HIV infection.

Accreditation following completion of injection administration training with Galderma is required to prescribe poly-l-lactic acid under the PBS. Patients must be referred from the HIV physician to the accredited injector.

polylactic acid 150 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9476R	2	..	..	*419.09	38.30	Sculptra [GA]

▪ DIAGNOSTIC AGENTS

URINE TESTS

▪ GLUCOSE AND KETONE INDICATOR URINE

Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

glucose and ketone indicator urine diagnostic strip, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3106L NP	2	2	..	*19.41	20.58	Keto-Diabur- Test 5000 [RD]

glucose and ketone indicator urine diagnostic strip, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3107M NP	2	2	..	*19.53	20.70	Keto-Diastix [BN]

▪ GLUCOSE INDICATOR URINE

Restricted benefit

For treatment of a patient identifying as Aboriginal or Torres Strait Islander

glucose indicator urine diagnostic strip, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3104J NP	2	2	..	*21.51	22.68	Diastix [BN]

OTHER DIAGNOSTIC AGENTS

Tests for diabetes

▪ GLUCOSE INDICATOR BLOOD

glucose indicator blood diagnostic strip, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10153J NP	‡1	5	..	50.56	38.30	Contour next [IK]

glucose indicator blood diagnostic strip, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10221Y NP	‡1	5	..	50.56	38.30	Dario [UH]

glucose indicator blood diagnostic strip, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10395D NP	‡1	5	..	50.56	38.30	Betachek C50 [NA]

glucose indicator blood diagnostic strip, 100

1503D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	50.56	38.30	Contour [IK]

glucose indicator blood diagnostic strip, 100

1519Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	50.56	38.30	BGStar [SW]

glucose indicator blood diagnostic strip, 100

2562W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	50.56	38.30	TRUEbalance [NX]

glucose indicator blood diagnostic strip, 100

2575M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	50.56	38.30	TRUEtrack [NX]

glucose indicator blood diagnostic strip, 100

2624D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	50.56	38.30	TRUEresult [NX]

glucose indicator blood diagnostic strip, 100

2979T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	50.56	38.30	Accu-Chek Performa [RP]

glucose indicator blood diagnostic strip, 100

8190C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	50.56	38.30	Accu-Chek Active [RP]

glucose indicator blood diagnostic strip, 100

8522M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	50.56	38.30	FreeStyle Optium [MS]

glucose indicator blood diagnostic strip, 100

9154T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	..	50.56	38.30	FreeStyle Lite [MS]

glucose indicator blood diagnostic strip, 50

10147C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*50.57	38.30	EasyMate II [WI]

glucose indicator blood diagnostic strip, 50

10216Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*50.57	38.30	Healthpro [IF]

glucose indicator blood diagnostic strip, 50

10223C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*50.57	38.30	GluNEO [IF]

glucose indicator blood diagnostic strip, 50

10724K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡2	5	..	*50.57	38.30	2in1 smart glucose test strips [UB]

glucose indicator blood diagnostic strip, 50

2263D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*50.57	38.30	Optium Omega [MS]

glucose indicator blood diagnostic strip, 50

2673Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*50.57	38.30	OneTouch Select [JJ]

glucose indicator blood diagnostic strip, 50

2860M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	..	*50.57	38.30	Betachek G5 [NA]

glucose indicator blood diagnostic strip, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2890D NP	2	5	..	*50.57	38.30	Betachek [NA]

glucose indicator blood diagnostic strip, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2914J NP	2	5	..	*43.67	38.30	Glucoflex-R [NA]

glucose indicator blood diagnostic strip, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3406G NP	2	5	..	*50.57	38.30	CareSens N [PB]

glucose indicator blood diagnostic strip, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3441D NP	2	5	..	*50.57	38.30	OneTouch Verio [JJ]

glucose indicator blood diagnostic strip, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5043K NP	2	5	..	*50.57	38.30	Accu-Chek Aviva [RP]

glucose indicator blood diagnostic strip, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8739Y NP	2	5	..	*50.57	38.30	Accu-Chek Go [RP]

glucose indicator blood diagnostic strip, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8749L NP	2	5	..	*50.57	38.30	GlucoDr [OZ]

glucose indicator blood diagnostic strip, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8759B NP	2	5	..	*50.57	38.30	CareSens [PB]

glucose indicator blood diagnostic strip, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8795X NP	2	5	..	*50.57	38.30	SensoCard [PX]

glucose indicator blood diagnostic strip, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9298J NP	2	5	..	*50.57	38.30	Bionime Rightest [QB]

glucose indicator blood diagnostic strip, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9471L NP	2	5	..	*50.57	38.30	MyGlucoHealth [EH]

▪ GLUCOSE INDICATOR BLOOD

Restricted benefit

Blood glucose monitoring

Clinical criteria:

Patient must be on insulin therapy.

glucose indicator blood diagnostic strip, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9300L NP	‡1	5	..	50.56	38.30	Accu-Chek Mobile [RP]

▪ GLUCOSE INDICATOR BLOOD

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Restricted benefit

Blood glucose monitoring

Clinical criteria:

Patient must be on insulin therapy, AND

Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

glucose indicator blood diagnostic strip, 100

9301M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	11	..	50.56	38.30	Accu-Chek Mobile [RP]

▪ GLUCOSE INDICATOR BLOOD

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit
Blood glucose monitoring
Clinical criteria:
Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

glucose indicator blood diagnostic strip, 100

10164Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	11	..	50.56	38.30	Contour next [IK]

glucose indicator blood diagnostic strip, 100

10222B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	11	..	50.56	38.30	Dario [UH]

glucose indicator blood diagnostic strip, 100

10394C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	11	..	50.56	38.30	Betachek C50 [NA]

glucose indicator blood diagnostic strip, 100

1518X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	11	..	50.56	38.30	Contour [IK]

glucose indicator blood diagnostic strip, 100

1520B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	11	..	50.56	38.30	BGStar [SW]

glucose indicator blood diagnostic strip, 100

2568E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	11	..	50.56	38.30	TRUEresult [NX]

glucose indicator blood diagnostic strip, 100

2571H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	11	..	50.56	38.30	TRUEbalance [NX]

glucose indicator blood diagnostic strip, 100

2602Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	11	..	50.56	38.30	TRUEtrack [NX]

glucose indicator blood diagnostic strip, 100

9257F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	11	..	50.56	38.30	Accu-Chek Performa [RP]

glucose indicator blood diagnostic strip, 100

9269W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	11	..	50.56	38.30	FreeStyle Lite [MS]

glucose indicator blood diagnostic strip, 100

9270X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	11	..	50.56	38.30	FreeStyle Optium [MS]

glucose indicator blood diagnostic strip, 100

9273C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	11	..	50.56	38.30	Accu-Chek Active [RP]

glucose indicator blood diagnostic strip, 50

10139P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	11	..	*50.57	38.30	EasyMate II [WI]

glucose indicator blood diagnostic strip, 50

10215P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	11	..	*50.57	38.30	Healthpro [IF]

glucose indicator blood diagnostic strip, 50

10217R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	11	..	*50.57	38.30	GluNEO [IF]

glucose indicator blood diagnostic strip, 50

10700E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡2	11	..	*50.57	38.30	2in1 smart glucose test strips [UB]

glucose indicator blood diagnostic strip, 50

2697Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	11	..	*50.57	38.30	OneTouch Select [JJ]

glucose indicator blood diagnostic strip, 50

3407H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	11	..	*50.57	38.30	CareSens N [PB]

glucose indicator blood diagnostic strip, 50

3442E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	11	..	*50.57	38.30	OneTouch Verio [JJ]

glucose indicator blood diagnostic strip, 50

5053Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	11	..	*50.57	38.30	Accu-Chek Aviva [RP]

glucose indicator blood diagnostic strip, 50

9263M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	11	..	*50.57	38.30	GlucoDr [OZ]

glucose indicator blood diagnostic strip, 50

9267R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	11	..	*50.57	38.30	Optium Omega [MS]

glucose indicator blood diagnostic strip, 50

9274D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	11	..	*50.57	38.30	Accu-Chek Go [RP]

glucose indicator blood diagnostic strip, 50

9276F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	11	..	*50.57	38.30	Betachek [NA]

glucose indicator blood diagnostic strip, 50

9277G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	11	..	*50.57	38.30	Betachek G5 [NA]

glucose indicator blood diagnostic strip, 50

9278H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	11	..	*50.57	38.30	CareSens [PB]

glucose indicator blood diagnostic strip, 50

9279J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	11	..	*43.67	38.30	Glucoflex-R [NA]

glucose indicator blood diagnostic strip, 50

9281L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	11	..	*50.57	38.30	SensoCard [PX]

glucose indicator blood diagnostic strip, 50

9297H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	11	..	*50.57	38.30	Bionime Rightest [QB]

glucose indicator blood diagnostic strip, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9472M	2	11	..	*50.57	38.30	MyGlucoHealth [EH]

GENERAL NUTRIENTS

OTHER NUTRIENTS

TRIGLYCERIDES LONG CHAIN

Note Carbzero is not nutritionally complete and is not intended for use as a sole source of nutrition.

Restricted benefit

Ketogenic diet

Clinical criteria:

Patient must have intractable seizures requiring treatment with a ketogenic diet; OR

Patient must have a glucose transport protein defect; OR

Patient must have pyruvate dehydrogenase deficiency.

Carbzero should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

triglycerides long chain oral liquid, 18 x 250 mL cartons

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10037G NP	2	5	..	*289.15	38.30	carbzero [VF]

TRIGLYCERIDES MEDIUM CHAIN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6147

Ketogenic diet

Clinical criteria:

Patient must have intractable seizures requiring treatment with a ketogenic diet; OR

Patient must have a glucose transport protein defect; OR

Patient must have pyruvate dehydrogenase deficiency.

Authority required (STREAMLINED)

6191

Dietary management of conditions requiring a source of medium chain triglycerides

Clinical criteria:

Patient must have chylous ascites; OR

Patient must have chylothorax; OR

Patient must have hyperlipoproteinaemia type 1; OR

Patient must have long chain fatty acid oxidation disorders; OR

Patient must have fat malabsorption due to liver disease; OR

Patient must have fat malabsorption due to short gut syndrome; OR

Patient must have fat malabsorption due to cystic fibrosis; OR

Patient must have fat malabsorption due to gastrointestinal disorders.

triglycerides medium chain oral liquid, 18 x 250 mL cartons

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10049X NP	2	5	..	*357.19	38.30	betaquik [VF]

TRIGLYCERIDES MEDIUM CHAIN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6181

Chylous ascites

Authority required (STREAMLINED)

6134

Chylothorax

Authority required (STREAMLINED)

6164

Fat malabsorption

Clinical criteria:

The condition must be due to liver disease; OR

The condition must be due to short gut syndrome; OR

The condition must be due to cystic fibrosis; OR

The condition must be due to gastrointestinal disorders.

Authority required (STREAMLINED)
6203
Hyperlipoproteinaemia type 1
Authority required (STREAMLINED)
6155
Intractable childhood epilepsy
Clinical criteria:
Patient must require a ketogenic diet.
Authority required (STREAMLINED)
6135
Cerebrospinal fluid glucose transporter defect
Clinical criteria:
Patient must require a ketogenic diet.
Authority required (STREAMLINED)
6146
Long chain fatty acid oxidation disorders

triglycerides medium chain oil: oral, 500 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3128P NP	2	5	..	*49.83	38.30	MCT Oil [SB]

triglycerides medium chain oral liquid, 250 mL bottle

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9327X NP	8	5	..	*191.01	38.30	Liquigen [SB]

Fat/carbohydrates/proteins/minerals/vitamins, combinations

▪ AMINO ACID SYNTHETIC FORMULA

Note Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

Authority required
Eosinophilic oesophagitis
Treatment Phase: Initial treatment for up to 3 months
Clinical criteria:
Patient must require an amino acid based formula as a component of a dietary elimination program.
Population criteria:
Patient must be 18 years of age or less.
Treatment criteria:
Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.
Treatment with oral steroids should not be commenced during the period of initial treatment.
Eosinophilic oesophagitis is demonstrated by the following criteria:
(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and
(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.
The date of birth of the patient must be included in the authority application.
Authority required
Eosinophilic oesophagitis
Treatment Phase: Continuing treatment
Clinical criteria:
Patient must have responded to an initial course of PBS-subsidised treatment.
Population criteria:
Patient must be 18 years of age or less.
Treatment criteria:
Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.
Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

amino acid synthetic formula oral liquid: powder for, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1521C NP	12	5	..	*500.85	38.30	Neocate Advance Vanilla [SB]

amino acid synthetic formula oral liquid: powder for, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2250K NP	12	5	..	*500.85	38.30	EleCare [AB]

▪ AMINO ACID SYNTHETIC FORMULA

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:

The condition must not be isolated infant colic or reflux, AND

Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:

The condition must not be isolated infant colic or reflux.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:

The condition must not be isolated infant colic or reflux.

Population criteria:

Patient must be older than 24 months of age.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:

Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

amino acid synthetic formula oral liquid: powder for, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1180D NP	8	5	..	*335.25	38.30	Neocate Advance Vanilla [SB]

amino acid synthetic formula oral liquid: powder for, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8574G NP	8	5	..	*335.25	38.30	EleCare [AB]

amino acid synthetic formula oral liquid: powder for, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8754R NP	8	5	..	*335.25	38.30	Neocate Advance [SB]

▪ AMINO ACID SYNTHETIC FORMULA

Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

Authority required

Cows' milk anaphylaxis

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux, AND

Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux, AND

Patient must have had failure to thrive prior to commencement with initial treatment.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux.

Population criteria:

Patient must be older than 24 months of age.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe intestinal malabsorption including short bowel syndrome

Clinical criteria:

Patient must have failed to respond to protein hydrolysate formulae; OR

Patient must have been receiving parenteral nutrition.

amino acid synthetic formula oral liquid: powder for, 400 g

1192R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	8	5	..	*335.25	38.30	Neocate Advance Vanilla [SB]

amino acid synthetic formula oral liquid: powder for, 400 g

8575H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	8	5	..	*335.25	38.30	EleCare [AB]

amino acid synthetic formula oral liquid: powder for, 400 g

8755T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	8	5	..	*335.25	38.30	Neocate Advance [SB]

▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required
Cows' milk protein enteropathy
Treatment Phase: Initial treatment for up to 6 months
Clinical criteria:
The condition must not be isolated infant colic or reflux, AND
Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.
Population criteria:
Patient must be up to the age of 24 months.
Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required
Severe cows' milk protein enteropathy with failure to thrive
Treatment Phase: Initial treatment for up to 6 months
Clinical criteria:
The condition must not be isolated infant colic or reflux.
Population criteria:
Patient must be up to the age of 24 months.
Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required
Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae
Treatment Phase: Initial treatment for up to 6 months
Clinical criteria:
The condition must not be isolated infant colic or reflux.
Population criteria:
Patient must be older than 24 months of age.
Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required
Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
Treatment Phase: Initial treatment for up to 6 months
Clinical criteria:
Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).
Population criteria:
Patient must be up to the age of 24 months.
Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
The name of the specialist and the date of birth of the patient must be included in the authority application.

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids oral liquid: powder for, 400 g

2246F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	8	5	..	*341.81	38.30	Neocate LCP [SB]

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids oral liquid: powder for, 400 g

9339M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	8	5	..	*341.81	38.30	EleCare LCP [AB]

▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS

Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

Authority required

Cows' milk anaphylaxis

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux, AND

Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux, AND

Patient must have had failure to thrive prior to commencement with initial treatment.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux.

Population criteria:

Patient must be older than 24 months of age.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

Population criteria:
Patient must be up to the age of 24 months.
Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe intestinal malabsorption including short bowel syndrome
Clinical criteria:
Patient must have failed to respond to protein hydrolysate formulae; OR
Patient must have been receiving parenteral nutrition.

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids oral liquid: powder for, 400 g

2560R NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*341.81	38.30	Neocate LCP [SB]

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids oral liquid: powder for, 400 g

9340N NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*341.81	38.30	EleCare LCP [AB]

▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

Note Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

Authority required

Eosinophilic oesophagitis
Treatment Phase: Initial treatment for up to 3 months
Clinical criteria:
Patient must require an amino acid based formula as a component of a dietary elimination program.
Population criteria:
Patient must be 18 years of age or less.
Treatment criteria:
Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.
Treatment with oral steroids should not be commenced during the period of initial treatment.
Eosinophilic oesophagitis is demonstrated by the following criteria:
(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and
(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.
The date of birth of the patient must be included in the authority application.

Authority required

Eosinophilic oesophagitis
Treatment Phase: Continuing treatment
Clinical criteria:
Patient must have responded to an initial course of PBS-subsidised treatment.
Population criteria:
Patient must be 18 years of age or less.
Treatment criteria:
Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.
Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g

1545H NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12	5	..	*510.57	38.30	Neocate Gold [SB]

▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required

Cows' milk protein enteropathy
Treatment Phase: Initial treatment for up to 6 months
Clinical criteria:
The condition must not be isolated infant colic or reflux, AND
Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.
Population criteria:
Patient must be up to the age of 24 months.
Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive
Treatment Phase: Initial treatment for up to 6 months
Clinical criteria:
The condition must not be isolated infant colic or reflux.
Population criteria:
Patient must be up to the age of 24 months.
Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae
Treatment Phase: Initial treatment for up to 6 months
Clinical criteria:
The condition must not be isolated infant colic or reflux.
Population criteria:
Patient must be older than 24 months of age.
Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
Treatment Phase: Initial treatment for up to 6 months
Clinical criteria:
Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).
Population criteria:
Patient must be up to the age of 24 months.
Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
The name of the specialist and the date of birth of the patient must be included in the authority application.

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g

5466Q
NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*341.81	38.30	Neocate Gold [SB]

▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

Authority required

Cows' milk anaphylaxis
Population criteria:
Patient must be up to the age of 24 months.
Treatment criteria:
Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.
Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.
The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Cows' milk protein enteropathy
Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux, AND

Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux, AND

Patient must have had failure to thrive prior to commencement with initial treatment.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux.

Population criteria:

Patient must be older than 24 months of age.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe intestinal malabsorption including short bowel syndrome

Clinical criteria:

Patient must have failed to respond to protein hydrolysate formulae; OR

Patient must have been receiving parenteral nutrition.

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g

5467R

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*341.81	38.30	Neocate Gold [SB]

▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

Authority required

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux, AND

Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux, AND

Patient must have had failure to thrive prior to commencement with initial treatment.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux.

Population criteria:

Patient must be older than 24 months of age.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Cows' milk anaphylaxis

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe intestinal malabsorption including short bowel syndrome

Clinical criteria:

Patient must have failed to respond to protein hydrolysate formulae; OR

Patient must have been receiving parenteral nutrition.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have responded to an initial course of PBS-subsidised treatment.

Population criteria:

Patient must be 18 years of age or less.

Treatment criteria:

Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g

2900P

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*341.81	38.30	Alfamino [NT]

▪ AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

Authority required

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:

The condition must not be isolated infant colic or reflux, AND

Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:

The condition must not be isolated infant colic or reflux.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:

The condition must not be isolated infant colic or reflux.

Population criteria:

Patient must be older than 24 months of age.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:

Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

Clinical criteria:

Patient must require an amino acid based formula as a component of a dietary elimination program.

Population criteria:

Patient must be 18 years of age or less.

Treatment criteria:

Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.

Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and

(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and

(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

The date of birth of the patient must be included in the authority application.

Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g

2928D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	8	5	..	*341.81	38.30	Alfamino [NT]

▪ PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6174

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Initial treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux, AND

Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

Authority required (STREAMLINED)

6193

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux, AND

Patient must have demonstrated a clinical improvement with the protein hydrolysate formula with medium chain triglycerides.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

Authority required (STREAMLINED)

6204

Cows' milk protein enteropathy and intolerance to soy protein

Clinical criteria:

The condition must not be isolated infant colic or reflux, AND

Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

Population criteria:

Patient must be older than 24 months of age.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist must be documented in the patient's medical records

Authority required (STREAMLINED)

6137

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist must be documented in the patient's medical records

Authority required (STREAMLINED)

6182

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist must be documented in the patient's medical records

Authority required (STREAMLINED)

6194

Biliary atresia

Authority required (STREAMLINED)

6157

Chronic liver failure with fat malabsorption

Authority required (STREAMLINED)

6205

Chylous ascites

Authority required (STREAMLINED)

6195

Cystic fibrosis

Authority required (STREAMLINED)

6158

Enterokinase deficiency

Authority required (STREAMLINED)

6166

Proven fat malabsorption

Authority required (STREAMLINED)

6148

Severe diarrhoea of greater than 2 weeks duration

Population criteria:

Patient must be aged less than 4 months.

Authority required (STREAMLINED)

6138

Severe intestinal malabsorption including short bowel syndrome

protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 450 g

8259Q

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*99.73	38.30	Aptamil Gold+ Pepti-Junior [NU]

▪ PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6174

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Initial treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux, AND

Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

Authority required (STREAMLINED)

6193

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Continuing treatment

Clinical criteria:

The condition must not be isolated infant colic or reflux, AND

Patient must have demonstrated a clinical improvement with the protein hydrolysate formula with medium chain triglycerides.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

Authority required (STREAMLINED)

6204

Cows' milk protein enteropathy and intolerance to soy protein

Clinical criteria:

The condition must not be isolated infant colic or reflux, AND

Patient must have failed to respond to a strict soy-based cows' milk protein free diet.

Population criteria:

Patient must be older than 24 months of age.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist must be documented in the patient's medical records

Authority required (STREAMLINED)

6137

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist must be documented in the patient's medical records

Authority required (STREAMLINED)

6182

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist must be documented in the patient's medical records

Authority required (STREAMLINED)

6194

Biliary atresia

Authority required (STREAMLINED)

6157

Chronic liver failure with fat malabsorption

Authority required (STREAMLINED)

6205

Chylous ascites

Authority required (STREAMLINED)

6195

Cystic fibrosis

Authority required (STREAMLINED)

6158

Enterokinase deficiency

Authority required (STREAMLINED)

6166

Proven fat malabsorption

Authority required (STREAMLINED)

6148

Severe diarrhoea of greater than 2 weeks duration

Population criteria:

Patient must be aged less than 4 months.

Authority required (STREAMLINED)

6138

Severe intestinal malabsorption including short bowel syndrome

Authority required (STREAMLINED)

6206

Chylothorax

protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2676W NP	8	5	..	*153.41	38.30	Alfaré [NT]

▪ TRIGLYCERIDES MEDIUM CHAIN FORMULA

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised.

Note Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

Restricted benefit

Dietary management of conditions requiring a source of medium chain triglycerides

Clinical criteria:

Patient must have fat malabsorption due to liver disease; OR

Patient must have fat malabsorption due to short gut syndrome; OR

Patient must have fat malabsorption due to cystic fibrosis; OR

Patient must have fat malabsorption due to gastrointestinal disorders.

triglycerides medium chain formula oral liquid, 8 x 500 mL pouches

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10375C NP	8	5	..	*823.73	38.30	Nutrini Peptisorb [SB]

triglycerides medium chain formula oral liquid: powder for, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10152H NP	8	5	..	*394.37	38.30	Monogen [SB]

triglycerides medium chain formula oral liquid: powder for, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10155L NP	8	5	..	*415.49	38.30	Lipistart [VF]

▪ TRIGLYCERIDES MEDIUM CHAIN FORMULA

Note No increase in the maximum number of repeats may be authorised.

Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

Note Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

Restricted benefit

Dietary management of conditions requiring a source of medium chain triglycerides

Clinical criteria:

Patient must have fat malabsorption due to liver disease; OR

Patient must have fat malabsorption due to short gut syndrome; OR

Patient must have fat malabsorption due to cystic fibrosis; OR

Patient must have fat malabsorption due to gastrointestinal disorders.

triglycerides medium chain formula oral liquid: powder for, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10154K NP	8	5	..	*384.69	38.30	Peptamen Junior [NT]

▪ TRIGLYCERIDES MEDIUM CHAIN FORMULA

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised.

Note Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

Restricted benefit

Hyperlipoproteinaemia type 1

Restricted benefit

Long chain fatty acid oxidation disorders

Restricted benefit

Chylous ascites

Restricted benefit

Chylothorax

triglycerides medium chain formula oral liquid: powder for, 400 g

1938B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	8	5	..	*415.49	38.30	Lipistart [VF]

triglycerides medium chain formula oral liquid: powder for, 400 g

8478F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	8	5	..	*394.37	38.30	Monogen [SB]

Carbohydrates

▪ AMYLOPECTIN MODIFIED LONG CHAIN

Restricted benefit

Glycogen storage disease

amylopectin modified long chain oral liquid: powder for, 30 x 60 g sachets

9386B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	4	5	..	*709.29	38.30	Glycosade [VF]

Amino acids/carbohydrates/minerals/vitamins, combinations

▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES

Authority required

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:

The condition must not be isolated infant colic or reflux, AND

Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:

The condition must not be isolated infant colic or reflux.

Population criteria:

Patient must be up to the age of 24 months.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

Clinical criteria:

The condition must not be isolated infant colic or reflux.

Population criteria:

Patient must be older than 24 months of age.

Treatment criteria:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months
Clinical criteria:
Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides).
Population criteria:
Patient must be up to the age of 24 months.
Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
The name of the specialist and the date of birth of the patient must be included in the authority application.

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required
Eosinophilic oesophagitis
Treatment Phase: Initial treatment for up to 3 months
Clinical criteria:
Patient must require an amino acid based formula as a component of a dietary elimination program.
Population criteria:
Patient must be 18 years of age or less.
Treatment criteria:
Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.
Treatment with oral steroids should not be commenced during the period of initial treatment.
Eosinophilic oesophagitis is demonstrated by the following criteria:
(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and
(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.
The date of birth of the patient must be included in the authority application.

Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides oral liquid: powder for, 400 g

10522T (NP)

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*352.61	38.30	Alfamino Junior [NT]

▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES

Note Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

Authority required
Cows' milk protein enteropathy
Treatment Phase: Continuing treatment
Clinical criteria:
The condition must not be isolated infant colic or reflux, AND
Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula.
Population criteria:
Patient must be up to the age of 24 months.
Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists.
The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required
Severe cows' milk protein enteropathy with failure to thrive
Treatment Phase: Continuing treatment
Clinical criteria:
The condition must not be isolated infant colic or reflux, AND
Patient must have had failure to thrive prior to commencement with initial treatment.
Population criteria:
Patient must be up to the age of 24 months.
Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists.
The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required
Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae
Treatment Phase: Continuing treatment
Clinical criteria:
The condition must not be isolated infant colic or reflux.
Population criteria:
Patient must be older than 24 months of age.
Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months.
The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required
Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein
Treatment Phase: Continuing treatment
Clinical criteria:
Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment.
Population criteria:
Patient must be up to the age of 24 months.
Treatment criteria:
Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist.
The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required
Cows' milk anaphylaxis
Population criteria:
Patient must be up to the age of 24 months.
Treatment criteria:
Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist.
Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.
The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required
Severe intestinal malabsorption including short bowel syndrome
Clinical criteria:
Patient must have failed to respond to protein hydrolysate formulae; OR
Patient must have been receiving parenteral nutrition.

Authority required
Eosinophilic oesophagitis
Treatment Phase: Continuing treatment
Clinical criteria:
Patient must have responded to an initial course of PBS-subsidised treatment.
Population criteria:
Patient must be 18 years of age or less.
Treatment criteria:
Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist.
Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides oral liquid: powder for, 400 g

10527C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	8	5	..	*352.61	38.30	Alfamino Junior [NT]

Milk substitutes

▪ MILK POWDER LACTOSE FREE FORMULA

Note No applications for increased maximum quantities and/or repeats will be authorised. No more than 1 application per patient will be authorised.

Authority required
Acute lactose intolerance in infants up to the age of 12 months. The date of birth of the patient must be included in the authority application

milk powder lactose free formula oral liquid: powder for, 900 g

8282X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	5	..	..	*102.38	38.30	S-26 LF [AS]

▪ MILK POWDER LACTOSE FREE FORMULA

Note No applications for increased maximum quantities and/or repeats will be authorised.

Authority required

Proven chronic lactose intolerance in infants up to the age of 12 months. The date of birth of the patient must be included in the authority application. Lactose intolerance must have been proven by either:
(a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or
(b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or
(c) hydrogen breath test

milk powder lactose free formula oral liquid: powder for, 900 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8283Y NP	5	5	..	*102.38	38.30	S-26 LF [AS]

▪ MILK POWDER LACTOSE FREE FORMULA PREDIGESTED

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required

Chronic lactose intolerance
Clinical criteria:
The condition must be proven to be lactose intolerance.
Population criteria:
Patient must be up to the age of 12 months.
Lactose intolerance must have been proven by either:
(a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or
(b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or
(c) hydrogen breath test.
The date of birth of the patient must be included in the authority application.

milk powder lactose free formula predigested oral liquid: powder for, 900 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2989H NP	5	5	..	*87.33	38.30	Aptamil Gold+ De-Lact [NU]

▪ MILK POWDER LACTOSE FREE FORMULA PREDIGESTED

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note No more than 1 application per patient will be authorised.

Authority required

Acute lactose intolerance
Population criteria:
Patient must be up to the age of 12 months.
The date of birth of the patient must be included in the authority application.

milk powder lactose free formula predigested oral liquid: powder for, 900 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2975N NP	5	..	..	*87.33	38.30	Aptamil Gold+ De-Lact [NU]

▪ MILK POWDER LACTOSE MODIFIED PREDIGESTED

Note No applications for increased maximum quantities and/or repeats will be authorised.

Authority required

Proven chronic lactose intolerance in children aged 1 year and over who are significantly malnourished. The date of birth of the patient must be included in the authority application. Lactose intolerance must have been proven by either:
(a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or
(b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or
(c) hydrogen breath test

milk powder lactose modified predigested oral liquid: powder for, 900 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2357C NP	3	10	..	*67.74	38.30	Digestelact [SJ]

▪ MILK POWDER LACTOSE MODIFIED PREDIGESTED

Note No applications for increased maximum quantities and/or repeats will be authorised. No more than 1 application per patient will be authorised.

Authority required

Acute lactose intolerance in children aged 1 year and over. The date of birth of the patient must be included in the authority application

milk powder lactose modified predigested oral liquid: powder for, 900 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2358D NP	3	1	..	*67.74	38.30	Digestelact [SJ]

▪ MILK POWDER SYNTHETIC LOW CALCIUM

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Restricted benefit
Hypercalcaemia
Population criteria:
Patient must be under the age of 4 years.

milk powder synthetic low calcium oral liquid: powder for, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3092R NP	8	5	..	*355.17	38.30	Locasol [SB]

Other combinations of nutrients

▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE

Restricted benefit
Phenylketonuria

amino acid formula with fat, carbohydrate without phenylalanine tablet: modified release, 4 x 110 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10683G NP	‡5	5	..	*1399.73	38.30	PKU Easy Microtabs [OH]

▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERAL AND TRACE ELEMENTS WITHOUT PHENYLALANINE

Restricted benefit
Phenylketonuria

amino acid formula with fat, carbohydrate, vitamins, mineral and trace elements without phenylalanine oral liquid: powder for, 30 x 34 g bottles

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10632N NP	4	5	..	*1539.45	38.30	PKU Easy Shake & Go [OH]

▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT METHIONINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID

Restricted benefit
Pyridoxine non-responsive homocystinuria

amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without methionine and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL cans

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3417W NP	4	5	..	*2390.41	38.30	HCU Anamix junior LQ [SB]

▪ AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE AND TYROSINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID

Restricted benefit
Tyrosinaemia

amino acid formula with fat, carbohydrate, vitamins, minerals and trace elements without phenylalanine and tyrosine, and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL cans

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9330C NP	4	5	..	*2390.41	38.30	TYR Anamix junior LQ [SB]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN

Restricted benefit
Proven glutaric aciduria type 1

amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 30 x 18 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10715Y NP	8	5	..	*2011.49	38.30	GA1 Anamix Junior [NU]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN

Restricted benefit

Proven glutaric aciduria type 1

amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 30 x 24 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9438R NP	4	5	..	*2011.57	38.30	GA gel [VF]

amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 30 x 25 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5484P NP	4	5	..	*3004.53	38.30	GA express 15 [VF]

amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2650L NP	8	5	..	*725.41	38.30	GA1 Anamix infant [SB]

amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 500 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10466W NP	9	5	..	*2933.10	38.30	XLYS, LOW TRY Maxamum [SB]

amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 500 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2646G NP	8	5	..	*1689.01	38.30	XLYS, LOW TRY Maxamaid [SB]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE

Restricted benefit

Pyridoxine non-responsive homocystinuria

AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE Oral liquid 125 mL, 30, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1548L NP	3	5	..	*2951.25	38.30	HCU Lophlex LQ 20 [SB]

amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 130 mL cans

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9133Q NP	4	5	..	*2951.29	38.30	HCU cooler 15 [VF]

amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 174 mL sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2640Y NP	4	5	..	*3886.09	38.30	HCU cooler 20 [VF]

amino acid formula with vitamins and minerals without methionine oral liquid, 30 x 87 mL sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2639X NP	4	5	..	*2011.57	38.30	HCU cooler 10 [VF]

amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 30 x 24 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8677Q NP	4	5	..	*2011.57	38.30	HCU gel [VF]

amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 30 x 25 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8744F NP	4	5	..	*2951.29	38.30	HCU express 15 [VF]

amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 500 g

8328H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	8	5	..	*1689.01	38.30	XMET Maxamaid [SB]

amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 500 g

8416Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	8	5	..	*2577.33	38.30	XMET Maxamum [SB]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE

Restricted benefit

Pyridoxine non-responsive homocystinuria

amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 30 x 36 g sachets

10693T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	4	5	..	*2011.57	38.30	HCU Anamix Junior [NU]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE

Restricted benefit

Pyridoxine non-responsive homocystinuria

Population criteria:

Patient must be an infant or a very young child.

amino acid formula with vitamins and minerals without methionine oral liquid: powder for, 400 g

8417B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	8	5	..	*725.41	38.30	HCU Anamix infant [SB]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE

Restricted benefit

Methylmalonic acidaemia

Restricted benefit

Propionic acidaemia

AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE, THREONINE and VALINE and low in ISOLEUCINE Oral liquid 130 mL, 30, 1

1923F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	4	5	..	*2951.29	38.30	MMA/PA cooler 15 [VF]

amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 30 x 24 g sachets

3444G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	4	5	..	*2011.57	38.30	MMA/PA gel [VF]

amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 30 x 25 g sachets

3443F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	4	5	..	*2951.29	38.30	MMA/PA express 15 [VF]

amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 400 g

8058D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	8	5	..	*725.41	38.30	MMA/PA Anamix infant [SB]

amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 500 g

8059E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	8	5	..	*1689.01	38.30	XMTVI Maxamaid [SB]

amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 500 g

8061G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	8	5	..	*2577.33	38.30	XMTVI Maxamum [SB]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE

Restricted benefit
Methylmalonic acidaemia
Restricted benefit
Propionic acidaemia

amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine oral liquid: powder for, 30 x 18 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10730R NP	8	5	..	*2011.49	38.30	MMA/PA Anamix Junior [NU]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE

Restricted benefit
Phenylketonuria

AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE Sachets 18.2 g, 60, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1411G NP	3	5	..	*1552.26	38.30	add-ins [SB]

AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE Sachets 34 g, 30, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1909L NP	4	5	..	*1952.21	38.30	PKU express 20 [VF]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 18 x 250 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8746H NP	5	5	..	*1243.28	38.30	Easiphen [SB]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 125 mL cans

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9021T NP	3	5	..	*1466.58	38.30	PKU Lophlex LQ 20 [SB]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 130 mL cans

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8846N NP	4	5	..	*1465.49	38.30	PKU Cooler 15 [VF]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 130 mL pouch

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10410X NP	4	5	..	*1465.49	38.30	PKU Air 15 [VF]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 174 mL cans

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2474F NP	4	5	..	*1952.21	38.30	PKU Cooler 20 [VF]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 174 mL pouch

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10411Y NP	4	5	..	*1952.21	38.30	PKU Air 20 [VF]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 85 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5483N NP	4	5	..	*999.73	38.30	PKU squeezie [VF]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 30 x 87 mL cans

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2382J NP	4	5	..	*976.33	38.30	PKU Cooler 10 [VF]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 36 x 125 mL cans

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9396M NP	4	5	..	*1202.25	38.30	PKU Anamix Junior LQ [SB]

amino acid formula with vitamins and minerals without phenylalanine oral liquid, 60 x 62.5 mL cans

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9397N NP	2	5	..	*1000.53	38.30	PKU Lophlex LQ 10 [SB]

amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 24 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8555G NP	4	5	..	*999.73	38.30	PKU gel [VF]

amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 25 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8591E NP	4	5	..	*1466.29	38.30	PKU express 15 [VF]

amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 27.8 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8804J NP	3	5	..	*1466.58	38.30	Lophlex [SB]

amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 50 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8727H NP	3	5	..	*1431.24	38.30	XP Maxamum [SB]

amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 500 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2738D NP	8	5	..	*833.89	38.30	XP Maxamaid [SB]

amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 500 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2739E NP	8	5	..	*1280.29	38.30	XP Maxamum [SB]

amino acid formula with vitamins and minerals without phenylalanine oral semi-solid, 36 x 109 g jars

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2806Q NP	3	5	..	*1754.31	38.30	PKU Lophlex Sensation 20 [SB]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE

Note Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

Restricted benefit
Phenylketonuria

amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 36 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10258X NP	4	5	..	*1000.93	38.30	PKU Anamix Junior [SB]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE

Restricted benefit
Tyrosinaemia

AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE and TYROSINE Oral liquid 125 mL, 30, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1547K NP	3	5	..	*2951.25	38.30	TYR Lophlex LQ 20 [SB]

amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 130 mL cans

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9132P NP	4	5	..	*2951.29	38.30	TYR cooler 15 [VF]

amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 174 mL sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2701E NP	4	5	..	*3886.09	38.30	TYR cooler 20 [VF]

amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid, 30 x 87 mL sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2674R NP	4	5	..	*2011.57	38.30	TYR cooler 10 [VF]

amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 24 g sachets

8631G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	4	5	..	*2011.57	38.30	TYR gel [VF]

amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 25 g sachets

8667E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	4	5	..	*2951.29	38.30	TYR express 15 [VF]

amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 400 g

8445L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	8	5	..	*725.41	38.30	TYR Anamix infant [SB]

amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 500 g

3078B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	8	5	..	*2577.33	38.30	XPhen, Tyr Maxamum [SB]

amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 500 g

8446M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	8	5	..	*1689.01	38.30	XPhen, Tyr Maxamaid [SB]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE

Note Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

Restricted benefit

Tyrosinaemia

amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 36 g sachets

10260B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	4	5	..	*2011.57	38.30	TYR Anamix Junior [SB]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE

Restricted benefit

Maple syrup urine disease

AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE Oral liquid 125 mL, 30, 1

1546J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	3	5	..	*2951.25	38.30	MSUD Lophlex LQ 20 [SB]

AMINO ACID FORMULA with VITAMINS and MINERALS without VALINE, LEUCINE and ISOLEUCINE Sachets 34 g, 30, 1

1914R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	4	5	..	*3897.25	38.30	MSUD express 20 [VF]

amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 130 mL cans

2375B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	4	5	..	*2951.29	38.30	MSUD cooler 15 [VF]

amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 174 mL pouches

2654Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	4	5	..	*3886.09	38.30	MSUD cooler 20 [VF]

amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid, 30 x 87 mL pouches

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2651M NP	4	5	..	*2011.57	38.30	MSUD cooler 10 [VF]

amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 24 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8592F NP	4	5	..	*2011.57	38.30	MSUD gel [VF]

amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 25 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8632H NP	4	5	..	*2951.29	38.30	MSUD express 15 [VF]

amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2380G NP	8	5	..	*725.41	38.30	MSUD Anamix infant [SB]

amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 500 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8057C NP	8	5	..	*2577.33	38.30	MSUD Maxamum [SB]

amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 500 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8260R NP	8	5	..	*1689.01	38.30	MSUD Maxamaid [SB]

amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 500 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8310J NP	4	5	..	*2546.21	38.30	MSUD AID III [SB]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE

Note Changes in vitamin D levels and amino acid composition have occurred with a recent formulation change.

Restricted benefit
Maple syrup urine disease

amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 36 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10259Y NP	4	5	..	*2011.57	38.30	MSUD Anamix Junior [SB]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE WITH FAT, CARBOHYDRATE AND TRACE ELEMENTS AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID

Restricted benefit
Maple syrup urine disease

amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexaenoic acid oral liquid, 36 x 125 mL cans

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9499Y NP	4	5	..	*2390.41	38.30	MSUD Anamix Junior LQ [SB]

▪ AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE

Restricted benefit
Phenylketonuria

amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine oral liquid: powder for, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8479G NP	8	5	..	*663.33	38.30	PKU Anamix infant [SB]

▪ AMINO ACID FORMULA WITHOUT PHENYLALANINE

Restricted benefit

Phenylketonuria

amino acid formula without phenylalanine 1 g tablet, 75

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8678R NP	24	5	..	*1350.69	38.30	Phlexy-10 [SB]

amino acid formula without phenylalanine 500 mg capsule, 200

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8554F NP	16	5	..	*1208.37	38.30	Phlexy-10 [SB]

amino acid formula without phenylalanine oral liquid: powder for, 30 x 20 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2347M NP	7	5	..	*1384.81	38.30	Phlexy-10 Drink Mix [SB]

▪ AMINO ACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE

Restricted benefit

Maple syrup urine disease

amino acid formula without valine, leucine and isoleucine containing 5 g of protein equivalent oral liquid: powder for, 30 x 6 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10161T NP	12	5	..	*3098.85	38.30	MSUD amino5 [VF]

▪ ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE

Restricted benefit

Peroxisomal biogenesis disorders

arachidonic acid and docosahexaenoic acid with carbohydrate containing 200 mg arachidonic acid and 100 mg docosahexaenoic acid oral liquid: powder for, 30 x 4 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10036F NP	4	5	..	*362.65	38.30	keyomega [VF]

▪ ARGININE WITH CARBOHYDRATE

Note Arginine with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.

Restricted benefit

Urea cycle disorders

arginine with carbohydrate containing 2 g arginine oral liquid: powder for, 30 x 4 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5482M NP	4	5	..	*726.85	38.30	Arginine 2000 [VF]

arginine with carbohydrate containing 5 g arginine oral liquid: powder for, 30 x 7.6 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10093F NP	4	5	..	*965.33	38.30	Arginine 5000 [VF]

arginine with carbohydrate containing 500 mg arginine oral liquid: powder for, 30 x 4 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9437Q NP	4	5	..	*485.89	38.30	Arginine 500 [VF]

▪ CARBOHYDRATE, FAT, VITAMINS, MINERALS AND TRACE ELEMENTS

Restricted benefit

Proven inborn errors of protein metabolism

Clinical criteria:

Patient must be unable to meet their energy requirements with permitted food and formulae.

carbohydrate, fat, vitamins, minerals and trace elements oral liquid: powder for, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8369L NP	8	5	..	*292.93	38.30	Energivit [SB]

▪ CARBOHYDRATES, FAT, VITAMINS, MINERALS, TRACE ELEMENTS AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID

Restricted benefit

Proven inborn errors of protein metabolism

Clinical criteria:

Patient must be unable to meet their energy requirements with permitted food and formulae.

carbohydrates, fat, vitamins, minerals, trace elements and supplemented with arachidonic acid and docosahexaenoic acid providing 100 kilocalories oral liquid: powder for 30 x 21.5 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10050Y NP	4	5	..	*235.81	38.30	basecal 100 [VF]

carbohydrates, fat, vitamins, minerals, trace elements and supplemented with arachidonic acid and docosahexaenoic acid providing 200 kilocalories oral liquid: powder for, 30 x 43 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10039J NP	4	5	..	*467.53	38.30	basecal 200 [VF]

▪ CITRULLINE

Note Citrulline is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism

Restricted benefit

Urea cycle disorders

Clinical criteria:

The treatment must be for preventing low plasma arginine levels; OR

The treatment must be for preventing low citrulline levels.

citrulline 1 g tablet, 300

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10736C NP	‡1	5	..	1196.73	38.30	Citrulline Easy [OH]

▪ CITRULLINE WITH CARBOHYDRATE

Note Citrulline with carbohydrate is not indicated for the treatment of arginase deficiency and other inborn errors of protein metabolism.

Restricted benefit

Urea cycle disorders in order to prevent low plasma arginine or citrulline levels

citrulline with carbohydrate containing 1 g citrulline oral liquid: powder for, 30 x 4 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5481L NP	4	5	..	*485.89	38.30	Citrulline 1000 [VF]

▪ CYSTINE WITH CARBOHYDRATE

Restricted benefit

Pyridoxine non-responsive homocystinuria

cystine with carbohydrate containing 500 mg cystine oral liquid: powder for, 30 x 4 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9164H NP	4	5	..	*485.89	38.30	Cystine 500 [VF]

▪ DOCOSAHEXAENOIC ACID WITH CARBOHYDRATE

Restricted benefit

Peroxisomal biogenesis disorders

docosahexaenoic acid with carbohydrate containing 200 mg docosahexaenoic acid oral liquid: powder for, 30 x 4g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10040K NP	4	5	..	*362.65	38.30	docomega [VF]

▪ ESSENTIAL AMINO ACIDS FORMULA

Restricted benefit

Gyrate atrophy of the choroid and retina

Restricted benefit

Urea cycle disorders

essential amino acids formula oral liquid: powder for, 2 x 200 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9329B NP	6	5	..	*1136.67	38.30	Essential Amino Acid Mix [SB]

▪ ESSENTIAL AMINO ACIDS FORMULA WITH MINERALS AND VITAMIN C

Restricted benefit
Gyrate atrophy of the choroid and retina
Restricted benefit
Urea cycle disorders

essential amino acids formula with minerals and vitamin C oral liquid: powder for, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2027Q NP	5	5	..	*597.63	38.30	Dialamine [SB]

▪ ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS

Restricted benefit
Gyrate atrophy of the choroid and retina
Restricted benefit
Urea cycle disorders

essential amino acids formula with vitamins and minerals oral liquid: powder for, 50 x 12.5 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9385Y NP	4	5	..	*1435.41	38.30	EAA Supplement [VF]

▪ GLYCINE WITH CARBOHYDRATE

Restricted benefit
Isovaleric acidaemia

glycine with carbohydrate containing 500 mg of glycine oral liquid: powder for, 30 x 4 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10195N NP	4	5	..	*511.29	38.30	Glycine500 [VF]

▪ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS

Restricted benefit
Phenylketonuria

glycomacropeptide and essential amino acids oral liquid, 12 x 500 mL bottles

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2712R NP	12	5	..	*1261.77	38.30	Camino Pro Restore [QH]

▪ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

Restricted benefit
Phenylketonuria

glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 54 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2696X NP	14	5	..	*860.09	38.30	Camino Pro Complete [QH]

glycomacropeptide and essential amino acids with vitamins and minerals bar, 7 x 81 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2644E NP	14	5	..	*1288.07	38.30	Camino Pro Complete [QH]

glycomacropeptide and essential amino acids with vitamins and minerals oral liquid: powder for, 30 x 49 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10652P NP	4	5	..	*1569.97	38.30	Camino Pro Bettermilk [QH]

▪ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

Note This product contains higher vitamin A levels than other PBS-listed glycomacropeptide products.

Restricted benefit
Phenylketonuria

glycomacropeptide and essential amino acids with vitamins and minerals containing 10 g protein oral liquid, 30 x 250 mL cartons

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10359F NP	4	5	..	*1072.13	38.30	PKU Glytactin RTD 10 [QH]

glycomacropeptide and essential amino acids with vitamins and minerals containing 15 g protein oral liquid, 30 x 250 mL cartons

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10332T NP	4	5	..	*1569.89	38.30	PKU Glytactin RTD 15 [QH]

▪ GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

Restricted benefit

Tyrosinaemia

glycomacropeptide and essential amino acids with vitamins and minerals 15 g protein equivalent oral liquid, 30 x 250 mL cartons

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10528D NP	4	5	..	*3098.89	38.30	Tylactin RTD [QH]

▪ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

Note Authorities for increased maximum quantities, up to a maximum of 11, may be authorised.

Restricted benefit

Ketogenic diet

Clinical criteria:

Patient must have intractable seizures requiring treatment with a ketogenic diet; OR

Patient must have a glucose transport protein defect; OR

Patient must have pyruvate dehydrogenase deficiency.

KetoCal 4:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydrate plus protein) oral liquid, 32 x 200 mL cartons

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10185C NP	5	5	..	*931.18	38.30	KetoCal 4:1 LQ [SB]

▪ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

Note Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.

Restricted benefit

Ketogenic diet

Clinical criteria:

Patient must have intractable seizures requiring treatment with a ketogenic diet; OR

Patient must have a glucose transport protein defect; OR

Patient must have pyruvate dehydrogenase deficiency.

KetoCal 3:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (3:1 ratio long chain fat to carbohydrate plus protein) oral liquid: powder for, 300 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2652N NP	24	5	..	*978.93	38.30	KetoCal 3:1 [SB]

▪ HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE

Note Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.

Restricted benefit

Ketogenic diet

Clinical criteria:

Patient must have intractable seizures requiring treatment with a ketogenic diet; OR

Patient must have a glucose transport protein defect; OR

Patient must have pyruvate dehydrogenase deficiency.

KetoCal 4:1 should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist.

high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (4:1 ratio long chain fat to carbohydate plus protein) oral liquid: powder for, 300 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9446E NP	24	5	..	*978.93	38.30	KetoCal 4:1 [SB]

▪ ISOLEUCINE WITH CARBOHYDRATE

Restricted benefit

Maple syrup urine disease

isoleucine with carbohydrate containing 1 g isoleucine oral liquid: powder for, 30 x 4 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9436P NP	4	5	..	*534.09	38.30	Isoleucine 1000 [VF]

isoleucine with carbohydrate containing 50 mg isoleucine oral liquid: powder for, 30 x 4 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9134R NP	4	5	..	*485.89	38.30	Isoleucine 50 [VF]

▪ MILK PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE

Restricted benefit

Patients with intractable seizures requiring treatment with a ketogenic diet

Restricted benefit

Glucose transport protein defects

Restricted benefit

Pyruvate dehydrogenase deficiency

Restricted benefit

Infants and young children with glucose-galactose intolerance and multiple monosaccharide intolerance

milk protein and fat formula with vitamins and minerals carbohydrate free oral liquid: powder for, 225 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8630F NP	24	5	..	*611.01	38.30	Carbohydrate Free Mixture [SB]

▪ PHENYLALANINE WITH CARBOHYDRATE

Restricted benefit

Tyrosinaemia

phenylalanine with carbohydrate containing 50 mg phenylalanine oral liquid: powder for, 30 x 4 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9384X NP	4	5	..	*485.89	38.30	Phenylalanine 50 [VF]

▪ PROTEIN FORMULA WITH AMINO ACIDS, CARBOHYDRATES, VITAMINS AND MINERALS WITHOUT PHENYLALANINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID

Restricted benefit

Phenylketonuria

protein formula with amino acids, carbohydrates, vitamins and minerals without phenylalanine, and supplemented with docosahexaenoic acid oral liquid, 30 x 130 mL pouches

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10658Y NP	4	5	..	*1538.61	38.30	PKU Easy [OH]

▪ SOY PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE

Restricted benefit

Patients with intractable seizures requiring treatment with a ketogenic diet

Restricted benefit

Glucose transport protein defects

Restricted benefit

Pyruvate dehydrogenase deficiency

Restricted benefit

Infants and young children with glucose-galactose intolerance and multiple monosaccharide intolerance

soy protein and fat formula with vitamins and minerals carbohydrate free oral liquid, 384 mL can

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8577K NP	120	5	..	*630.93	38.30	RCF [AB]

▪ TRIGLYCERIDES LONG CHAIN WITH GLUCOSE POLYMER

Restricted benefit

Proven inborn errors of protein metabolism

Clinical criteria:

Patient must be unable to meet their energy requirements with permitted food and formulae.

triglycerides long chain with glucose polymer oral liquid, 18 x 250 mL cans

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9308X NP	6	5	..	*314.19	38.30	ProZero [VF]

triglycerides long chain with glucose polymer oral liquid, 27 x 200 mL cartons

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10189G NP	2	5	..	*170.57	38.30	Sno-Pro [SB]

triglycerides long chain with glucose polymer oral liquid, 6 x 1 L bottles

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9309Y NP	4	5	..	*279.01	38.30	ProZero [VF]

▪ TRIGLYCERIDES MEDIUM CHAIN AND LONG CHAIN WITH GLUCOSE POLYMER

Restricted benefit

Proven inborn errors of protein metabolism

Clinical criteria:

Patient must be unable to meet their energy requirements with permitted food and formulae.

triglycerides medium chain and long chain with glucose polymer oral liquid: powder for, 400 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
3136C NP	8	5	..	*270.69	38.30	Duocal [SB]

▪ TRIGLYCERIDES MEDIUM CHAIN FORMULA

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.

Authority required (STREAMLINED)

6165

Chylous ascites

Authority required (STREAMLINED)

6192

Chylothorax

Authority required (STREAMLINED)

6173

Fat malabsorption

Clinical criteria:

The condition must be due to liver disease; OR

The condition must be due to short gut syndrome; OR

The condition must be due to cystic fibrosis; OR

The condition must be due to gastrointestinal disorders.

Authority required (STREAMLINED)

6156

Hyperlipoproteinaemia type 1

Authority required (STREAMLINED)

6136

Long chain fatty acid oxidation disorders

triglycerides medium chain formula oral liquid: powder for, 30 x 16 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9383W NP	4	5	..	*229.49	38.30	MCT Pro-Cal [VF]

▪ TYROSINE WITH CARBOHYDRATE

Restricted benefit

Phenylketonuria

tyrosine with carbohydrate containing 1 g tyrosine oral liquid: powder for, 30 x 4 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9165J NP	4	5	..	*485.89	38.30	Tyrosine 1000 [VF]

▪ VALINE WITH CARBOHYDRATE

Restricted benefit

Maple syrup urine disease

valine with carbohydrate containing 1 g valine oral liquid: powder for, 30 x 4 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9434M NP	4	5	..	*534.09	38.30	Valine 1000 [VF]

valine with carbohydrate containing 50 mg valine oral liquid: powder for, 30 x 4 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9135T NP	4	5	..	*485.89	38.30	Valine 50 [VF]

▪ VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE

Note FruitiVits must only be used under strict supervision of a dietitian and a paediatrician.

Restricted benefit

Dietary management of conditions requiring a highly restrictive therapeutic diet

Clinical criteria:

Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, AND

Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

Population criteria:

Patient must be aged 3 years or older.

vitamins, minerals and trace elements with carbohydrate oral liquid: powder for, 30 x 6 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10149E NP	1	5	..	274.02	38.30	FruitiVits [VF]

▪ VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE

Note Paediatric Seravit must only be used under strict supervision of a dietitian and a paediatrician.

Restricted benefit

Dietary management of conditions requiring a highly restrictive therapeutic diet

Clinical criteria:

Patient must have insufficient vitamin and mineral intake due to a specific diagnosis requiring a highly restrictive therapeutic diet, AND

Patient must be unable to adequately meet vitamin, mineral and trace element needs with other proprietary vitamin and mineral preparations.

Population criteria:

Patient must be an infant or a child.

vitamins, minerals and trace elements with carbohydrate oral liquid: powder for, 200 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9328Y NP	6	5	..	*363.93	38.30	Paediatric Seravit [SB]

▪ WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE

Authority required (STREAMLINED)

6190

Chronic renal failure

Clinical criteria:

Patient must require treatment with a low protein and a low phosphorus diet; OR

Patient must require treatment with a low protein, low phosphorus and low potassium diet.

Population criteria:

Patient must be an infant or a young child.

whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose oral liquid: powder for, 10 x 100 g sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9382T NP	9	5	..	*1406.25	38.30	RenaStart [VF]

whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose oral liquid: powder for, 6 x 400 g cans

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2870C NP	4	5	..	*1499.49	38.30	Renastart [VF]

▪ WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE

Authority required (STREAMLINED)

6190
Chronic renal failure
Clinical criteria:
Patient must require treatment with a low protein and a low phosphorus diet; OR
Patient must require treatment with a low protein, low phosphorus and low potassium diet.
Population criteria:
Patient must be an infant or a young child.

whey protein formula supplemented with amino acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose oral liquid: powder for, 400 g

8587Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	16	5	..	*1007.25	38.30	Kindergen [SB]

Palliative Care

Palliative

ALIMENTARY TRACT AND METABOLISM

STOMATOLOGICAL PREPARATIONS

STOMATOLOGICAL PREPARATIONS

Other agents for local oral treatment

BENZYDAMINE

Authority required (STREAMLINED)

6197

Painful mouth

Clinical criteria:

Patient must be receiving palliative care.

benzydamine hydrochloride 0.15% mouthwash, 500 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5385K NP	‡1	3	..	23.51	24.68	Difflam [IA]

DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

BELLADONNA AND DERIVATIVES, PLAIN

Belladonna alkaloids, semisynthetic, quaternary ammonium compounds

HYOSCINE BUTYLBROMIDE

Authority required (STREAMLINED)

6207

For use in patients receiving palliative care

hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5317W NP	6	3	..	*98.61	38.30	Buscopan [BY]

PROPULSIVES

Propulsives

METOCLOPRAMIDE

Authority required (STREAMLINED)

6084

Nausea or gastric stasis

Clinical criteria:

Patient must be receiving palliative care.

metoclopramide hydrochloride 10 mg/2 mL injection, 10 x 2 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10762K NP	4	..	..	*33.25	34.42	Maxolon [IA]

DRUGS FOR CONSTIPATION

DRUGS FOR CONSTIPATION

Contact laxatives

BISACODYL

Restricted benefit

Constipation

Clinical criteria:

Patient must be receiving palliative care.

bisacodyl 10 mg suppository, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5303D NP	3	3	..	*23.04	24.21	[a] Petrus Bisacodyl Suppositories [PP]
			[B]1.29	*24.33	24.21	[a] Dulcolax [BY]

bisacodyl 10 mg suppository, 12

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5304E NP	3	3	..	*20.76	21.93	Petrus Bisacodyl Suppositories [PP]

bisacodyl 5 mg tablet: enteric, 200

5301B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	3	..	17.11	18.28	Lax-Tab [AE]

Bulk-forming laxatives

▪ RHAMNUS FRANGULA + STERCULIA

Restricted benefit

Constipation

Clinical criteria:

Patient must be receiving palliative care.

rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g

5322D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	3	..	26.90	28.07	Normacol Plus [NE]

Osmotically acting laxatives

▪ MACROGOL-3350

Note Pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 510 g and pharmaceutical benefits that have the form macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

6170

Constipation

Clinical criteria:

Patient must be receiving palliative care.

macrogol-3350 1 g/g oral liquid: powder for, 30 x 17 g sachets

2351R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	3	..	*30.97	32.14	[a] Herron ClearLax [ON]

macrogol-3350 1 g/g oral liquid: powder for, 510 g

5426N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	3	..	*30.97	32.14	[a] OsmoLax [KY]

▪ MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE

Authority required (STREAMLINED)

6171

Constipation

Clinical criteria:

Patient must be receiving palliative care.

macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets

5389P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*30.97	32.14	[a] APO-MACROGOL plus ELECTROLYTES [TX] [a] LaxaCon [EA] [a] Macrovic [RF] [a] Movicol [NE]	[a] Chemists' Own Macrogol with Electrolytes [RW] [a] lax-sachets [AE] [a] Molaxole [HM]

macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL

10127B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	3	..	*24.13	25.30	Movicol Liquid [NE]

Enemas

▪ BISACODYL

Restricted benefit

Constipation

Clinical criteria:

Patient must be receiving palliative care.

bisacodyl 10 mg/5 mL enema, 25 x 5 mL

5302C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	3	..	37.83	38.30	Bisalax [AS]

▪ SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM

Restricted benefit

Constipation

Clinical criteria:

Patient must be receiving palliative care.

sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5331N NP	2	3	..	*32.91	34.08	[a] Micolette [AE]	[a] Microlax [JT]

Peripheral opioid receptor antagonists

▪ METHYLNALTREXONE

Authority required (STREAMLINED)

6180

Opioid-induced constipation

Clinical criteria:

The treatment must be in combination with oral laxatives, AND

Patient must be receiving palliative care, AND

Patient must have failed to respond to laxatives.

METHYLNALTREXONE Solution for injection containing methylnaltrexone bromide 12 mg in 0.6 mL, 7

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5424L NP	1	..	..	263.13	38.30	Relistor [LM]

methylnaltrexone bromide 12 mg/0.6 mL injection, 0.6 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5423K NP	7	..	..	*263.13	38.30	Relistor [LM]

▪ MUSCULO-SKELETAL SYSTEM

▪ ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS

Acetic acid derivatives and related substances

▪ DICLOFENAC

Restricted benefit

Severe pain

Clinical criteria:

Patient must be receiving palliative care.

diclofenac sodium 100 mg suppository, 20

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5363G NP	2	3	..	*26.85	28.02	Voltaren 100 [NV]

diclofenac sodium 25 mg tablet: enteric, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5361E NP	2	3	..	*13.79	14.96	[a] APO-Diclofenac [TX] [a] Clonac 25 [RW] [a] Diclofenac-GA [ED] [a] Fenac 25 [AF]	[a] Chem mart Diclofenac [CH] [a] Diclofenac AN [EA] [a] Diclofenac Sandoz [SZ] [a] Terry White Chemists Diclofenac [TW]
			[B]2.44	*16.23	14.96	[a] Voltaren 25 [NV]	

diclofenac sodium 50 mg tablet: enteric, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
5362F NP	1	3	..	12.75	13.92	[a] APO-Diclofenac [TX] [a] Clonac 50 [RW] [a] Diclofenac-GA [ED] [a] Fenac [AF]	[a] Chem mart Diclofenac [CH] [a] Diclofenac AN [EA] [a] Diclofenac Sandoz [SZ] [a] Terry White Chemists Diclofenac [TW]
			[B]2.45	15.20	13.92	[a] Voltaren 50 [NV]	

▪ INDOMETHACIN

Restricted benefit

Severe pain

Clinical criteria:

Patient must be receiving palliative care.

indomethacin 100 mg suppository, 20

5378C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	3	..	*24.41	25.58	Indocid [AS]

indomethacin 25 mg capsule, 50

5377B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	3	..	*16.03	17.20	[a] Arthrexin [AF]
			[B]4.04	*20.07	17.20	[a] Indocid [AS]

Propionic acid derivatives

▪ IBUPROFEN

Restricted benefit

Severe pain

Clinical criteria:

Patient must be receiving palliative care.

ibuprofen 400 mg tablet, 30

5368M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	3	3	..	*17.28	18.45	Brufen [GO]

▪ NAPROXEN

Restricted benefit

Severe pain

Clinical criteria:

Patient must be unable to take a solid dose form of a non-steroidal anti-inflammatory agent.

Treatment criteria:

Patient must be undergoing palliative care.

naproxen 125 mg/5 mL oral liquid, 474 mL

5397C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	3	..	120.60	38.30	Phebra Naproxen Suspension [PL]

▪ NAPROXEN

Restricted benefit

Severe pain

Clinical criteria:

Patient must be receiving palliative care.

naproxen 1 g tablet: modified release, 28

5348L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	3	..	16.98	18.15	[a] Proxen SR 1000 [IY]
			[B]1.12	18.10	18.15	[a] Naprosyn SR1000 [IX]

naproxen 250 mg tablet, 50

5345H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	3	..	*17.69	18.86	[a] Inza 250 [AF]
			[B]2.24	*19.93	18.86	[a] Naprosyn [IX]

naproxen 500 mg tablet, 50

5346J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	3	..	15.79	16.96	[a] Inza 500 [AF]
			[B]1.12	16.91	16.96	[a] Naprosyn [IX]

naproxen 750 mg tablet: modified release, 28

5347K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	3	..	15.34	16.51	[a] Proxen SR 750 [IY]
			[B]1.06	16.40	16.51	[a] Naprosyn SR750 [IX]

▪ NAPROXEN

Note Naproxen sodium 550 mg is approximately equivalent to 500 mg of naproxen acid.

Restricted benefit

Severe pain

Clinical criteria:

Patient must be receiving palliative care.

naproxen sodium 550 mg tablet, 50

5353R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	3	..	15.94	17.11	[a] Crysanal [IY]
			[B]1.89	17.83	17.11	[a] Anaprox 550 [IX]

NERVOUS SYSTEM

ANALGESICS

OPIOIDS

Natural opium alkaloids

MORPHINE

Caution The risk of drug dependence is high.

Note Telephone approvals are limited to 1 month's therapy.

Authority required

Chronic severe disabling pain

Clinical criteria:

Patient must be receiving palliative care, AND

The condition must be unresponsive to non-opioid analgesics.

morphine sulfate 200 mg tablet: modified release, 28

5391R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	115.81	38.30	MS Contin [MF]

MORPHINE

Caution The risk of drug dependence is high.

Note Telephone approvals are limited to 1 month's therapy.

Authority required

Severe disabling pain

Clinical criteria:

Patient must be receiving palliative care, AND

The condition must be unresponsive to non-opioid analgesics.

morphine sulfate 10 mg tablet, 20

5393W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	17.84	19.01	Sevredol [MF]

morphine sulfate 20 mg tablet, 20

5394X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	2	..	18.66	19.83	Sevredol [MF]

Phenylpiperidine derivatives

FENTANYL

Caution The risk of drug dependence is high.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Breakthrough pain

Treatment Phase: Initial treatment for dose titration

Clinical criteria:

Patient must have cancer, AND

Patient must have pain directly attributable to cancer, AND

Patient must be assessed as receiving adequate management of their persistent pain with opioids, AND

Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR

The treatment must be used as short acting opioids are considered clinically inappropriate; OR

Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

Treatment criteria:

Patient must be undergoing palliative care.

FENTANYL Lozenge 1200 micrograms (as citrate), 9

5405L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	95.58	38.30	Actiq [TB]

FENTANYL Lozenge 1600 micrograms (as citrate), 9

5406M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	95.58	38.30	Actiq [TB]

FENTANYL Lozenge 200 micrograms (as citrate), 9

5401G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	95.58	38.30	Actiq [TB]

FENTANYL Lozenge 400 micrograms (as citrate), 9

5402H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	95.58	38.30	Actiq [TB]

FENTANYL Lozenge 600 micrograms (as citrate), 9

5403J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	95.58	38.30	Actiq [TB]

FENTANYL Lozenge 800 micrograms (as citrate), 9

5404K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	95.58	38.30	Actiq [TB]

fentanyl 100 microgram tablet: sublingual, 10

10601Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	86.44	38.30	Abstral [FK]

fentanyl 200 microgram tablet: sublingual, 10

10600X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	86.44	38.30	Abstral [FK]

fentanyl 300 microgram tablet: sublingual, 10

10606F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	86.44	38.30	Abstral [FK]

fentanyl 400 microgram tablet: sublingual, 10

10603C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	86.44	38.30	Abstral [FK]

fentanyl 600 microgram tablet: sublingual, 10

10604D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	86.44	38.30	Abstral [FK]

fentanyl 800 microgram tablet: sublingual, 10

10612M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	..	..	86.44	38.30	Abstral [FK]

▪ FENTANYL

Caution The risk of drug dependence is high.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Breakthrough pain

Treatment Phase: Initial treatment for dose titration

Clinical criteria:

Patient must have cancer, AND

Patient must have pain directly attributable to cancer, AND

Patient must be assessed as receiving adequate management of their persistent pain with opioids, AND

Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR

The treatment must be used as short acting opioids are considered clinically inappropriate; OR
Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.
Treatment criteria:
Patient must be undergoing palliative care.

fentanyl 100 microgram tablet: orally disintegrating, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10729Q NP	2	..	..	*71.84	38.30	Fentora [TB]

fentanyl 200 microgram tablet: orally disintegrating, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10697B NP	2	..	..	*71.84	38.30	Fentora [TB]

fentanyl 400 microgram tablet: orally disintegrating, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10739F NP	2	..	..	*71.84	38.30	Fentora [TB]

fentanyl 600 microgram tablet: orally disintegrating, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10722H NP	2	..	..	*71.84	38.30	Fentora [TB]

fentanyl 800 microgram tablet: orally disintegrating, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10723J NP	2	..	..	*71.84	38.30	Fentora [TB]

▪ FENTANYL

Caution The risk of drug dependence is high.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note For first continuing supply, applications for increased repeats for up to 3 months' supply may be authorised.

Note Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

Note Telephone approvals are limited to 1 months' therapy.

Authority required
Breakthrough pain
Treatment Phase: Continuing treatment
Clinical criteria:
Patient must have cancer, AND
Patient must have pain directly attributable to cancer, AND
Patient must be assessed as receiving adequate management of their persistent pain with opioids, AND
Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR
The treatment must be used as short acting opioids are considered clinically inappropriate; OR
Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.
Treatment criteria:
Patient must be undergoing palliative care.

FENTANYL Lozenge 1200 micrograms (as citrate), 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5411T NP	2	..	..	*574.58	38.30	Actiq [TB]

FENTANYL Lozenge 1600 micrograms (as citrate), 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5412W NP	2	..	..	*574.58	38.30	Actiq [TB]

FENTANYL Lozenge 200 micrograms (as citrate), 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5407N NP	2	..	..	*574.58	38.30	Actiq [TB]

FENTANYL Lozenge 400 micrograms (as citrate), 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5408P NP	2	..	..	*574.58	38.30	Actiq [TB]

FENTANYL Lozenge 600 micrograms (as citrate), 30

5409Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*574.58	38.30	Actiq [TB]

FENTANYL Lozenge 800 micrograms (as citrate), 30

5410R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*574.58	38.30	Actiq [TB]

fentanyl 100 microgram tablet: sublingual, 30

10602B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*461.06	38.30	Abstral [FK]

fentanyl 200 microgram tablet: sublingual, 30

10607G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*461.06	38.30	Abstral [FK]

fentanyl 300 microgram tablet: sublingual, 30

10610K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*461.06	38.30	Abstral [FK]

fentanyl 400 microgram tablet: sublingual, 30

10608H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*461.06	38.30	Abstral [FK]

fentanyl 600 microgram tablet: sublingual, 30

10613N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*461.06	38.30	Abstral [FK]

fentanyl 800 microgram tablet: sublingual, 30

10611L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*461.06	38.30	Abstral [FK]

▪ FENTANYL

Caution The risk of drug dependence is high.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note For first continuing supply, applications for increased repeats for up to 3 months' supply may be authorised.

Note Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

Note Telephone approvals are limited to 1 months' therapy.

Authority required

Breakthrough pain

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have cancer, AND

Patient must have pain directly attributable to cancer, AND

Patient must be assessed as receiving adequate management of their persistent pain with opioids, AND

Patient must have previously experienced inadequate pain relief following adequate doses of short acting opioids for the treatment of breakthrough pain; OR

The treatment must be used as short acting opioids are considered clinically inappropriate; OR

Patient must have previously experienced adverse effects following the use of short acting opioids for breakthrough pain.

Treatment criteria:

Patient must be undergoing palliative care.

fentanyl 100 microgram tablet: orally disintegrating, 28

10684H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*430.80	38.30	Fentora [TB]

fentanyl 200 microgram tablet: orally disintegrating, 28

10698C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	..	..	*430.80	38.30	Fentora [TB]

fentanyl 400 microgram tablet: orally disintegrating, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10737D NP	2	..	..	*430.80	38.30	Fentora [TB]

fentanyl 600 microgram tablet: orally disintegrating, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10713W NP	2	..	..	*430.80	38.30	Fentora [TB]

fentanyl 800 microgram tablet: orally disintegrating, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10738E NP	2	..	..	*430.80	38.30	Fentora [TB]

Diphenylpropylamine derivatives

▪ METHADONE

Caution The risk of drug dependence is high.

Note Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

Note Telephone approvals are limited to 1 month's therapy.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Chronic severe disabling pain

Treatment Phase: Initial treatment, for up to 3 months

Clinical criteria:

Patient must be receiving palliative care, AND

The condition must be unresponsive to non-opioid analgesics.

methadone hydrochloride 5 mg/mL oral liquid, 200 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5399E NP	1	2	..	21.83	23.00	Aspen Methadone Syrup [QA]

▪ METHADONE

Caution The risk of drug dependence is high.

Note Where consultation with a palliative care specialist or service has occurred, applications for increased repeats for up to 3 months' supply may be authorised.

Note Telephone approvals are limited to 1 month's therapy.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required

Chronic severe disabling pain

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must be receiving palliative care, AND

The condition must be unresponsive to non-opioid analgesics.

methadone hydrochloride 5 mg/mL oral liquid, 200 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5400F NP	1	..	..	21.83	23.00	Aspen Methadone Syrup [QA]

OTHER ANALGESICS AND ANTIPYRETICS

Anilides

▪ PARACETAMOL

Restricted benefit

Analgesia or fever

Clinical criteria:

Patient must be receiving palliative care, AND

Patient must be intolerant to alternative therapy.

paracetamol 500 mg suppository, 24

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5319Y NP	4	3	..	*81.37	38.30	Panadol [GC]

paracetamol 665 mg tablet: modified release, 96

5343F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	3	..	*17.89	19.06	Osteomol 665 Paracetamol [CR]

ANTIEPILEPTICS

ANTIEPILEPTICS

Benzodiazepine derivatives

CLONAZEPAM

Note No increase in the maximum number of repeats may be authorised.

Authority required

Myoclonus

Clinical criteria:

The treatment must be for prophylaxis or prevention of the indication, AND

Patient must be receiving palliative care.

clonazepam 2 mg tablet, 100

5338Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	3	..	21.13	22.30	[a] Paxam 2 [AF]
			[B]1.68	22.81	22.30	[a] Rivotril [RO]

clonazepam 2.5 mg/mL oral liquid, 10 mL

5339B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	3	..	*17.93	19.10	Rivotril [RO]

clonazepam 500 microgram tablet, 100

5337X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	3	..	16.11	17.28	[a] Paxam 0.5 [AF]
			[B]1.48	17.59	17.28	[a] Rivotril [RO]

PSYCHOLEPTICS

ANXIOLYTICS

Benzodiazepine derivatives

DIAZEPAM

Note No increase in the maximum number of repeats may be authorised.

Authority required

Anxiety

Clinical criteria:

Patient must be receiving palliative care.

diazepam 2 mg tablet, 50

5355W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	11.43	12.60	[a] Antenex 2 [AF]	[a] APO-Diazepam [TX]
						[a] Ranzepam [RA]	[a] Valpam 2 [RW]

diazepam 5 mg tablet, 50

5356X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	11.53	12.70	[a] Antenex 5 [AF]	[a] APO-Diazepam [TX]
						[a] Ranzepam [RA]	[a] Valpam 5 [RW]
			[B]2.19	13.72	12.70	[a] Valium [RO]	

OXAZEPAM

Note No increase in the maximum number of repeats may be authorised.

Authority required

Anxiety

Clinical criteria:

Patient must be receiving palliative care.

oxazepam 15 mg tablet, 25

5371Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	3	..	*13.27	14.44	[a] Alepam 15 [AF]
			[B]5.32	*18.59	14.44	[a] Serepax [QA]

oxazepam 30 mg tablet, 25

5372R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*12.59	13.76	[a] Alepam 30 [AF] [a] Murelax [RW]	[a] APO-Oxazepam [TX]
			[B]4.66	*17.25	13.76	[a] Serepax [QA]	

HYPNOTICS AND SEDATIVES

Benzodiazepine derivatives

▪ NITRAZEPAM

Note No increase in the maximum number of repeats may be authorised.

Authority required

Insomnia

Clinical criteria:

Patient must be receiving palliative care.

nitrazepam 5 mg tablet, 25

5359C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	3	..	*13.65	14.82	[a] Alodorm [AF]
			[B]2.48	*16.13	14.82	[a] Mogadon [IA]

▪ TEMAZEPAM

Note No increase in the maximum number of repeats may be authorised.

Authority required

Insomnia

Clinical criteria:

Patient must be receiving palliative care.

temazepam 10 mg tablet, 25

5375X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*12.05	13.22	[a] APO-Temazepam [TX] [a] Temtabs [FM]	[a] Temaze [AF]
			[B]6.96	*19.01	13.22	[a] Normison [QA]	

Highly Specialised Drugs Program (Private Hospital)

BLOOD AND BLOOD FORMING ORGANS

ANTIHEMORRHAGICS

VITAMIN K AND OTHER HEMOSTATICS

Other systemic hemostatics

ELTROMBOPAG

Note Eltrombopag is not PBS-subsidised as an alternative to splenectomy.
Any queries concerning the arrangements to prescribe eltrombopag may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authority to prescribe eltrombopag should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001
Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

Note Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.
No applications for increased repeats will be authorised.

Note No applications for increased repeats will be authorised.

Authority required

Initial (new patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:

(1) Splenectomised and:

(a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and

(b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;

OR

(2) Not splenectomised and:

(a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and

(b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and

(c) in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:

(a) a platelet count of less than or equal to 20,000 million per L;

OR

(b) a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],

(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and

(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion

Authority required

Initial (grandfather patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with eltrombopag prior to 1 November 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time eltrombopag was commenced.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and

(4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion

Authority required

Continuing therapy or re-initiation after a break in therapy

First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with eltrombopag during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised eltrombopag,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include:

(1) a completed authority prescription form, and

(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and

(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The most recent platelet count must be no more than one month old at the time of application.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone

Authority required

Second and subsequent applications for continuing therapy

Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with eltrombopag and who continues to display a response to treatment with eltrombopag.

For the purposes of this restriction, a continuing response to treatment with eltrombopag is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with eltrombopag,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

Platelet counts must be no more than 1 month old at the time of application.

Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

eltrombopag 25 mg tablet, 28

5827Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	1558.93	Revolade [NV]

eltrombopag 50 mg tablet, 28

5828R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	3070.93	Revolade [NV]

▪ ROMIPLOSTIM

Note Romiplostim is not PBS-subsidised as an alternative to splenectomy.

Any queries concerning the arrangements to prescribe romiplostim may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe romiplostim should be forwarded to:

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

Note Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note Special Pricing Arrangements apply.

Authority required

Initial (new patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:

(1) Splenectomised and:

(a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and

(b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;

OR

(2) Not splenectomised and:

(a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and

(b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and

(c) in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:

(a) a platelet count of less than or equal to 20,000 million per L;

OR

(b) a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],

(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and

(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

Authority required

Initial (grandfather patients)

Initial PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with romiplostim prior to 1 April 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time romiplostim was commenced.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and

(4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

For patients whose dose of romiplostim had been stable for at least 4 weeks at the time of the initial application for PBS-subsidy, the medical practitioner should request sufficient number of vials based on the weight of the patient and dose (microgram/kg/week) to provide up to 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where the patient is in the titration phase of treatment with romiplostim, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

Authority required

Continuing therapy or re-initiation after a break in therapy

First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with romiplostim during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised romiplostim,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include:

(1) a completed authority prescription form, and

(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and

(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The most recent platelet count must be no more than one month old at the time of application.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

Authority required

Second and subsequent applications for continuing therapy

Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with romiplostim and who continues to display a response to treatment with romiplostim.

For the purposes of this restriction, a continuing response to treatment with romiplostim is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with romiplostim,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

Platelet counts must be no more than 1 month old at the time of application.

Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

romiplostim 250 microgram injection, 1 vial

9697J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	972.71	Nplate [AN]

romiplostim 500 microgram injection, 1 vial

9699L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	1904.18	Nplate [AN]

ANTIANEMIC PREPARATIONS

OTHER ANTIANEMIC PREPARATIONS

Other antianemic preparations

DARBEPOETIN ALFA

Authority required

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

darbepoetin alfa 10 microgram/0.4 mL injection, 4 x 0.4 mL syringes

6320P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*358.75	Aranesp [AN]

darbepoetin alfa 100 microgram/0.5 mL injection, 0.5 mL syringe

6492Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	8	5	..	*2536.37	Aranesp SureClick [AN]

darbepoetin alfa 100 microgram/0.5 mL injection, 4 x 0.5 mL syringes

6326Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*2536.41	Aranesp [AN]

darbepoetin alfa 150 microgram/0.3 mL injection, 0.3 mL syringe

6493R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	8	5	..	*3756.21	Aranesp SureClick [AN]

darbepoetin alfa 150 microgram/0.3 mL injection, 4 x 0.3 mL syringes

6365B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*3756.21	Aranesp [AN]

darbepoetin alfa 20 microgram/0.5 mL injection, 0.5 mL syringe

6488L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	8	5	..	*669.57	Aranesp SureClick [AN]

darbepoetin alfa 20 microgram/0.5 mL injection, 4 x 0.5 mL syringes

6321Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*669.49	Aranesp [AN]

darbepoetin alfa 30 microgram/0.3 mL injection, 4 x 0.3 mL syringes

6322R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*913.37	Aranesp [AN]

darbepoetin alfa 40 microgram/0.4 mL injection, 0.4 mL syringe

6489M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	8	5	..	*1104.85	Aranesp SureClick [AN]

darbepoetin alfa 40 microgram/0.4 mL injection, 4 x 0.4 mL syringes

6323T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1104.85	Aranesp [AN]

darbepoetin alfa 50 microgram/0.5 mL injection, 4 x 0.5 mL syringes

6324W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1354.87	Aranesp [AN]

darbepoetin alfa 60 microgram/0.3 mL injection, 0.3 mL syringe

6490N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	8	5	..	*1582.77	Aranesp SureClick [AN]

darbepoetin alfa 60 microgram/0.3 mL injection, 4 x 0.3 mL syringes

6325X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1582.75	Aranesp [AN]

darbepoetin alfa 80 microgram/0.4 mL injection, 0.4 mL syringe

6491P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	8	5	..	*2068.53	Aranesp SureClick [AN]

darbepoetin alfa 80 microgram/0.4 mL injection, 4 x 0.4 mL syringes

6438W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*2068.53	Aranesp [AN]

▪ EPOETIN ALFA

Authority required

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

epoetin alfa 10 000 units/mL injection, 6 x 1 mL syringes

6207Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1918.71	Eprex 10000 [JC]

epoetin alfa 1000 units/0.5 mL injection, 6 x 0.5 mL syringes

6251B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*282.89	Eprex 1000 [JC]

epoetin alfa 20 000 units/0.5 mL injection, 6 x 0.5 mL syringes

6434P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*3729.13	Eprex 20,000 [JC]

epoetin alfa 2000 units/0.5 mL injection, 6 x 0.5 mL syringes

6204M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*517.53	Eprex 2000 [JC]

epoetin alfa 3000 units/0.3 mL injection, 6 x 0.3 mL syringes

6205N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*665.83	Eprex 3000 [JC]

epoetin alfa 40 000 units/mL injection, 1 mL syringe

6339P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1238.23	Eprex 40,000 [JC]

epoetin alfa 4000 units/0.4 mL injection, 6 x 0.4 mL syringes

6206P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*846.05	Eprex 4000 [JC]

epoetin alfa 5000 units/0.5 mL injection, 6 x 0.5 mL syringes

6302Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1051.41	Eprex 5000 [JC]

epoetin alfa 6000 units/0.6 mL injection, 6 x 0.6 mL syringes

6303R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1239.31	Eprex 6000 [JC]

epoetin alfa 8000 units/0.8 mL injection, 6 x 0.8 mL syringes

6305W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1593.45	Eprex 8000 [JC]

▪ EPOETIN BETA

Authority required

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

epoetin beta 10 000 units/0.6 mL injection, 6 x 0.6 mL syringes

6485H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1918.71	NeoRecormon [RO]

epoetin beta 2000 units/0.3 mL injection, 6 x 0.3 mL syringes

6480C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*517.53	NeoRecormon [RO]

epoetin beta 3000 units/0.3 mL injection, 6 x 0.3 mL syringes

6481D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*665.83	NeoRecormon [RO]

epoetin beta 4000 units/0.3 mL injection, 6 x 0.3 mL syringes

6482E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*846.05	NeoRecormon [RO]

epoetin beta 5000 units/0.3 mL injection, 6 x 0.3 mL syringes

6483F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1051.43	NeoRecormon [RO]

epoetin beta 6000 units/0.3 mL injection, 6 x 0.3 mL syringes

6484G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1239.31	NeoRecormon [RO]

▪ EPOETIN LAMBDA

Note Epoetin lambda should only be administered by the intravenous route.

Authority required

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

epoetin lambda 10 000 units/mL injection, 6 x 1 mL syringes

9595B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1820.21	Novicrit [SZ]

epoetin lambda 1000 units/0.5 mL injection, 6 x 0.5 mL syringes

9685R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*268.37	Novicrit [SZ]

epoetin lambda 2000 units/mL injection, 6 x 1 mL syringes

9686T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*490.65	Novicrit [SZ]

epoetin lambda 3000 units/0.3 mL injection, 6 x 0.3 mL syringes

9687W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*631.15	Novicrit [SZ]

epoetin lambda 4000 units/0.4 mL injection, 6 x 0.4 mL syringes

9688X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*801.89	Novicrit [SZ]

epoetin lambda 5000 units/0.5 mL injection, 6 x 0.5 mL syringes

9588P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*996.61	Novicrit [SZ]

epoetin lambda 6000 units/0.6 mL injection, 6 x 0.6 mL syringes

9590R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1176.55	Novicrit [SZ]

epoetin lambda 8000 units/0.8 mL injection, 6 x 0.8 mL syringes

9593X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1512.05	Novicrit [SZ]

▪ METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA

Authority required

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

methoxy polyethylene glycol-epoetin beta 100 microgram/0.3 mL injection, 1 x 0.3 mL syringe

9577C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1147.81	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 120 microgram/0.3 mL injection, 1 x 0.3 mL syringe

9578D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1321.49	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 200 microgram/0.3 mL injection, 1 x 0.3 mL syringe

9579E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1875.01	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 30 microgram/0.3 mL injection, 1 x 0.3 mL syringe

9574X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*371.67	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 360 microgram/0.6 mL injection, 1 x 0.6 mL syringe

9580F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*3207.13	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 50 microgram/0.3 mL injection, 1 x 0.3 mL syringe

9575Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*614.85	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 75 microgram/0.3 mL injection, 1 x 0.3 mL syringe

9576B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*892.19	Mircera [RO]

CARDIOVASCULAR SYSTEM

ANTIHYPERTENSIVES

OTHER ANTIHYPERTENSIVES

Antihypertensives for pulmonary arterial hypertension

AMBRISENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition, AND

The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR

Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Patients who have previously received PBS-subsidised treatment with this drug for this condition under the Continuing treatment (all patients) prior to 1 May 2016 are eligible to continue PBS subsidised treatment with this drug under this criteria.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

ambrisentan 10 mg tablet, 30

9649W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	2779.58	Volibris [GK]

ambrisentan 5 mg tablet, 30

9648T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	2779.58	Volibris [GK]

▪ BOSENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.
The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.
The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.
The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition, AND

The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR

Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Patients who have previously received PBS-subsidised treatment with this drug for this condition under the Continuing treatment (all patients) prior to 1 May 2016 are eligible to continue PBS subsidised treatment with this drug under this criteria.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

bosentan 125 mg tablet, 60

6430K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	2779.58	Tracleer [AT]

▪ BOSENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.
The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.
The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.
The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition, AND

The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR

Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Patients who have previously received PBS-subsidised treatment with this drug for this condition under the Continuing treatment (all patients) prior to 1 May 2016 are eligible to continue PBS subsidised treatment with this drug under this criteria.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Cessation of treatment (all patients)

Clinical criteria:

Patient must have received approval for initial PBS-subsidised treatment with this agent, AND

Patient must have not responded to prior PBS-subsidised therapy with this agent, AND

The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services

Complex Drugs
Reply Paid 9826
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bosentan 62.5 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6429J	1	..	..	2779.58	Tracleer [AT]

▪ EPOPROSTENOL

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 micrograms (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and

(4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 micrograms (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients) or Initial 2 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition, AND

The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
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Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR

Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Patients who have previously received PBS-subsidised treatment with this drug for this condition under the Continuing treatment (all patients) prior to 1 May 2016 are eligible to continue PBS subsidised treatment with this drug under this criteria.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

EPOPROSTENOL SODIUM Powder for I.V. infusion 1.5 mg (base) infusion administration set, 1

5042J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	77.48	[a] Flolan Kit [GK]

EPOPROSTENOL SODIUM Powder for I.V. infusion 500 micrograms (base) infusion administration set, 1

5036C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	43.54	[a] Flolan Kit [GK]

epoprostenol 1.5 mg injection, 1 vial

10129D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	77.48	[a] Veletri [AT]

epoprostenol 500 microgram injection, 1 vial

10111E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	43.54	[a] Veletri [AT]

▪ ILOPROST

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with this agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III drug-induced PAH, AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note Special Pricing Arrangements apply.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III drug-induced PAH and a mean right atrial pressure greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III drug-induced PAH with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

Patient must have WHO Functional Class IV drug-induced PAH, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note Special Pricing Arrangements apply.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or drug-induced PAH and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and

(4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note Special Pricing Arrangements apply.

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition, AND

The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR

Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Patients who have previously received PBS-subsidised treatment with this drug for this condition under the Continuing treatment (all patients) prior to 1 May 2016 are eligible to continue PBS subsidised treatment with this drug under this criteria.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

iloprost 20 microgram/2 mL inhalation: solution, 30 x 2 mL ampoules

6456T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	432.17	Ventavis [BN]

▪ MACITENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

A maximum of 5 repeats will be authorised.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition, AND

The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR

Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Patients who have previously received PBS-subsidised treatment with this drug for this condition under the Continuing treatment (all patients) prior to 1 May 2016 are eligible to continue PBS subsidised treatment with this drug under this criteria.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

macitentan 10mg tablet, 30

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Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
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Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
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Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition, AND

The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the

same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR

Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Patients who have previously received PBS-subsidised treatment with this drug for this condition under the Continuing treatment (all patients) prior to 1 May 2016 are eligible to continue PBS subsidised treatment with this drug under this criteria.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

sildenafil 20 mg tablet, 90

9605M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	542.29	[a] APO-Sildenafil PHT [TX] [a] Sildenafil AN PHT 20 [EA] [a] Sildenafil Sandoz PHT 20 [SZ]	[a] Revatio [PF] [a] SILDENAFIL-DRx [RZ]

▪ TADALAFIL

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition, AND

The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR

Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Patients who have previously received PBS-subsidised treatment with this drug for this condition under the Continuing treatment (all patients) prior to 1 May 2016 are eligible to continue PBS subsidised treatment with this drug under this criteria.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

tadalafil 20 mg tablet, 56

1304P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	879.00	Adcirca [LY]

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

HYPOTHALAMIC HORMONES

Somatostatin and analogues

▪ LANREOTIDE

Authority required

Acromegaly

Clinical criteria:

The condition must be active, AND

Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, AND

The treatment must be after failure of other therapy including dopamine agonists; OR

The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR

The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, AND

The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose), AND

The treatment must cease if IGF1 is not lower after 3 months of treatment.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

lanreotide 30 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack

6332G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	11	..	*1471.93	Somatuline LA [IS]

▪ LANREOTIDE

Authority required

Acromegaly

Clinical criteria:

The condition must be active, AND

Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, AND

The treatment must be after failure of other therapy including dopamine agonists; OR

The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR

The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, AND

The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), AND

The treatment must cease if IGF1 is not lower after 3 months of treatment.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Authority required

Functional carcinoid tumour

Clinical criteria:

The condition must be causing intractable symptoms, AND

Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, AND

Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, AND

The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

lanreotide 120 mg injection, 1 syringe

6425E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	..	*4302.93	Somatuline Autogel [IS]

lanreotide 60 mg injection, 1 syringe

6423C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	..	*2602.43	Somatuline Autogel [IS]

lanreotide 90 mg injection, 1 syringe

6424D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	..	*3447.93	Somatuline Autogel [IS]

▪ OCTREOTIDE

Authority required

Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND

(a) after failure of other therapy including dopamine agonists; or

(b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or

(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.

In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks. Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Treatment must cease if IGF1 is not lower after 3 months treatment at a dose of 100 micrograms 3 times daily

Authority required

Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate.

Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose

octreotide 100 microgram/mL injection, 5 x 1 mL ampoules

6228T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	18	11	..	*1283.31	[a] Hospira Pty Limited [HH] [a] Octreotide (SUN) [RA]	[a] Octreotide MaxRx [GQ] [a] Sandostatin 0.1 [NV]

octreotide 50 microgram/mL injection, 5 x 1 mL ampoules

6227R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	18	11	..	*650.79	[a] Hospira Pty Limited [HH] [a] Octreotide (SUN) [RA]	[a] Octreotide MaxRx [GQ] [a] Sandostatin 0.05 [NV]

octreotide 500 microgram/mL injection, 5 x 1 mL ampoules

6229W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	18	11	..	*6241.41	[a] Hospira Pty Limited [HH] [a] Octreotide (SUN) [RA]	[a] Octreotide MaxRx [GQ] [a] Sandostatin 0.5 [NV]

▪ OCTREOTIDE

Authority required

Acromegaly

Clinical criteria:

The condition must be controlled with octreotide immediate release injections, AND

The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), AND

The treatment must cease if IGF1 is not lower after 3 months of treatment.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

Authority required

Functional carcinoid tumour

Clinical criteria:

Patient must have achieved symptom control on octreotide immediate release injections, AND

The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

Authority required

Vasoactive intestinal peptide secreting tumour (VIPoma)

Clinical criteria:

Patient must have achieved symptom control on octreotide immediate release injections, AND

The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

octreotide 10 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10566D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*2660.65	Sandostatin LAR [NV]

octreotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10549F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*3526.55	Sandostatin LAR [NV]

octreotide 30 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10558Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*4401.85	Sandostatin LAR [NV]

ANTIINFECTIVES FOR SYSTEMIC USE

ANTIBACTERIALS FOR SYSTEMIC USE

MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

Macrolides

AZITHROMYCIN

Authority required

Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre

azithromycin 600 mg tablet, 8

6221K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*122.13	Zithromax [PF]

CLARITHROMYCIN

Authority required

Mycobacterium avium complex infection

clarithromycin 500 mg tablet, 100

6152T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	2	..	45.68	APO-Clarithromycin [TX]

ANTIMYCOBACTERIALS

DRUGS FOR TREATMENT OF TUBERCULOSIS

Antibiotics

RIFABUTIN

Authority required

Treatment of Mycobacterium avium complex infections in HIV-positive patients

Authority required

Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre

rifabutin 150 mg capsule, 30

6195C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	4	5	..	*646.53	Mycobutin [PF]

ANTIVIRALS FOR SYSTEMIC USE

DIRECT ACTING ANTIVIRALS

Nucleosides and nucleotides excl. reverse transcriptase inhibitors

GANCICLOVIR

Authority required

Cytomegalovirus disease
Treatment Phase: Prophylaxis
Clinical criteria:
Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.

Authority required

Cytomegalovirus disease
Treatment Phase: Prophylaxis
Clinical criteria:
Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

ganciclovir 500 mg injection, 5 vials

6136Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	1	..	*560.21	Cymevene [RO]

RIBAVIRIN

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 12 weeks.

Population criteria:

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

ribavirin 400 mg tablet, 28

10623D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	2	..	152.53	Ibavyr [IX]

ribavirin 600 mg tablet, 28

10675W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	2	..	225.33	Ibavyr [IX]

▪ RIBAVIRIN

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 24 weeks.

Population criteria:

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

ribavirin 400 mg tablet, 28

10635R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	..	152.53	Ibavyr [IX]

ribavirin 600 mg tablet, 28

10637W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	..	225.33	Ibavyr [IX]

▪ VALACICLOVIR

Authority required

Cytomegalovirus infection and disease

Treatment Phase: Prophylaxis

Clinical criteria:

Patient must have undergone a renal transplant, AND

Patient must be at risk of cytomegalovirus disease.

valaciclovir 500 mg tablet, 100

6280M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*443.73	[a] APO-Valaciclovir [TX] [a] Valtrex [RW]	[a] Valaciclovir RBX [RA] [a] Zelitrex [RF]

▪ VALGANCICLOVIR

Authority required

Cytomegalovirus infection and disease

Treatment Phase: Prophylaxis

Clinical criteria:

Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

valganciclovir 450 mg tablet, 60

6357N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*4313.95	Valcyte [RO]

valganciclovir 50 mg/mL oral liquid: powder for, 100 mL

9675F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	11	5	..	*#4395.72	Valcyte [RO]

Protease inhibitors

▪ BOCEPREVIR

Note No increase in the maximum quantity or number of units may be authorised.

Note Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

Authority required

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease, AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C, AND

The treatment must be in combination with peginterferon alfa and ribavirin, AND

The treatment must be limited to a maximum duration of 32 weeks in patients without hepatic cirrhosis who were partial responders or relapsers to the prior course of interferon based therapy for hepatitis C; OR

The treatment must be limited to a maximum duration of 44 weeks in patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy for hepatitis C; OR

The treatment must be limited to a maximum duration of 44 weeks for all patients with hepatic cirrhosis, AND

The treatment must cease after the first 8 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 12, AND

The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24.

Population criteria:

Patient must be 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.

For patients without hepatic cirrhosis who were partial responders or relapsers to the prior course of interferon based therapy, a maximum of 7 repeats may be prescribed.

For patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy, a maximum of 10 repeats may be prescribed.

For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed.

Authority required

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease, AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND

The treatment must be in combination with peginterferon alfa and ribavirin, AND

The treatment must be limited to a maximum duration of 24 weeks in patients without hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 44 weeks in patients with hepatic cirrhosis, AND

The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24.

Population criteria:

Patient must be 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.

For patients without hepatic cirrhosis, a maximum of 5 repeats may be prescribed.

For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed.

boceprevir 200 mg capsule, 336

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2435E	1	10	..	3966.93	Victrelis [MK]

▪ SIMEPREVIR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

Authority required

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease, AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND

The treatment must be in combination with peginterferon alfa and ribavirin, AND

The treatment must be limited to a maximum duration of 12 weeks, AND

The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is 25 IU/mL or greater.

Population criteria:

Patient must be aged 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised simeprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.

Authority required

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease, AND

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C, AND

The treatment must be in combination with peginterferon alfa and ribavirin, AND

The treatment must be limited to a maximum duration of 12 weeks, AND

The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is 25 IU/mL or greater.

Population criteria:

Patient must be 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised simeprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.

simeprevir sodium 150 mg capsule, 7

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
10197Q	6	..	..	*14912.67	Olysio [JC]

Other antivirals

▪ DACLATASVIR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection
Clinical criteria:
Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
The treatment must be limited to a maximum duration of 24 weeks.

daclatasvir 30 mg tablet, 28

10630L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	..	7713.60	Daklinza [BQ]

daclatasvir 60 mg tablet, 28

10631M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	..	7713.60	Daklinza [BQ]

▪ DACLATASVIR

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection
Clinical criteria:
Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
The treatment must be limited to a maximum duration of 12 weeks.

daclatasvir 30 mg tablet, 28

10643E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	2	..	7713.60	Daklinza [BQ]

daclatasvir 60 mg tablet, 28

10644F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	2	..	7713.60	Daklinza [BQ]

▪ LEDIPASVIR + SOFOSBUVIR

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection
Clinical criteria:
Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
The treatment must be limited to a maximum duration of 8 weeks.

ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

10653Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	1	..	22113.60	Harvoni [GI]

▪ LEDIPASVIR + SOFOSBUVIR

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection
Clinical criteria:
Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
The treatment must be limited to a maximum duration of 12 weeks.

ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

10672Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	2	..	22113.60	Harvoni [GI]

▪ LEDIPASVIR + SOFOSBUVIR

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection
Clinical criteria:
Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
The treatment must be limited to a maximum duration of 24 weeks.

ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

10679C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	22113.60	Harvoni [GI]

▪ PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection
Clinical criteria:
Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
The treatment must be limited to a maximum duration of 12 weeks.

paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56], 4 x 28

10749R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	..	13900.06	Viekira Pak [VE]

▪ PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR & RIBAVIRIN

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection
Clinical criteria:
Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
The treatment must be limited to a maximum duration of 12 weeks.
Population criteria:
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 200 mg tablet [168], 1 pack

10753Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	..	13900.06	Viekira Pak-RBV [VE]

paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 600 mg tablet [56], 1 pack

10750T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	..	13900.06	Viekira Pak-RBV [VE]

▪ PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR & RIBAVIRIN

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 24 weeks.

Population criteria:

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 200 mg tablet [168], 1 pack

10761J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	..	13900.06	Viekira Pak-RBV [VE]

paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 600 mg tablet [56], 1 pack

10773B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	..	13900.06	Viekira Pak-RBV [VE]

▪ SOFOSBUVIR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 12 weeks.

sofosbuvir 400 mg tablet, 28

10654R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	2	..	19344.68	Sovaldi [GI]

▪ SOFOSBUVIR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 24 weeks.

sofosbuvir 400 mg tablet, 28

10676X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	..	19344.68	Sovaldi [GI]

▪ ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

▪ ANTINEOPLASTIC AGENTS

ANTIMETABOLITES

Pyrimidine analogues

▪ AZACITIDINE

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Authority required

Myelodysplastic syndrome

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR

The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS).

Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:

a. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR

b. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR

c. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR

d. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR

e. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR

f. Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

a. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR

b. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR

c. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR

d. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

The first authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and

(c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and

(d) a copy of the full blood examination report; and

(e) a copy of the pathology report detailing the cytogenetics demonstrating intermediate-2 or high risk disease according to the International Prognostic Scoring System (IPSS); and

(f) a signed patient acknowledgment form.

No more than 3 cycles will be authorised.

Authority required

Chronic Myelomonocytic Leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder.

The first authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and

(c) a copy of the bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia ; and

(d) a copy of the full blood examination report; and

(e) a signed patient acknowledgement.

No more than 3 cycles will be authorised.

Authority required

Acute Myeloid Leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

The first authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and

(c) a copy of the bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and

(d) a copy of the full blood examination report; and

(e) a signed patient acknowledgement.

No more than 3 cycles will be authorised.

azacitidine 100 mg injection, 1 vial

6100C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
14	2	..	*5219.13	[a] Azadine [RZ]	[a] Vidaza [CJ]

▪ AZACITIDINE

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Myelodysplastic syndrome
Treatment Phase: Continuing treatment
Clinical criteria:
The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR
The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS), AND
Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
Patient must not have progressive disease.
Applications for continuing therapy may be made by telephone.
Up to 6 cycles will be authorised.

Authority required

Chronic Myelomonocytic Leukaemia
Treatment Phase: Continuing treatment
Clinical criteria:
The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder, AND
Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
Patient must not have progressive disease.
Applications for continuing therapy may be made by telephone.
Up to 6 cycles will be authorised.

Authority required

Acute Myeloid Leukaemia
Treatment Phase: Continuing treatment
Clinical criteria:
The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification, AND
Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
Patient must not have progressive disease.
Applications for continuing therapy may be made by telephone.
Up to 6 cycles will be authorised.

azacitidine 100 mg injection, 1 vial

6138C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
14	5	..	*5219.13	[a] Azadine [RZ]	[a] Vidaza [CJ]

CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

Anthracyclines and related substances

▪ DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL

Authority required

Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive mucocutaneous involvement

Authority required

Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive visceral involvement

doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial

6249X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	5	..	*1747.89	[a] Caelyx [JC]	[a] Liposomal Doxorubicin SUN [RA]

OTHER ANTINEOPLASTIC AGENTS

Monoclonal antibodies

▪ RITUXIMAB

Note Risk of end-organ damage or mortality includes a minimum of one of the following:
Glomerulonephritis with risk of progression
Risk to sight including scleritis/episcleritis, sudden visual loss, uveitis, retinal changes (vasculitis/thrombosis/exudates/haemorrhage)
Bronchial/subglottic obstruction
Pulmonary haemorrhage

Parenchymal lung disease
Sensory neural hearing loss
Recurrent sinonasal disease requiring recurrent surgical interventions
Meningitis, organic confusion, seizures, stroke, cord lesion, cranial nerve palsy, sensory peripheral neuropathy, motor mononeuritis multiplex

Note Patients could be considered contraindicated, refractory, or unable to tolerate cyclophosphamide for one of the following reasons:
Cyclophosphamide is contraindicated as per the TGA approved Product Information;
Cyclophosphamide is not recommended due to the need to preserve gonad function;
Patient experiences severe toxicity to cyclophosphamide that warrants cessation of treatment;
Patient has life- or organ-threatening deterioration at any time during treatment with cyclophosphamide, where the deterioration is thought to be due to severe uncontrolled active vasculitis;
Commencing a further treatment cycle with cyclophosphamide would exceed the maximum cumulative dose of cyclophosphamide of 25g; or
Patient's condition with this indication is persistent despite at least 3 months therapy with cyclophosphamide.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment.

Authority required
Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)
Treatment Phase: Induction of remission
Clinical criteria:
The treatment must be for the induction of remission, AND
Patient must not have previously received this drug for this condition; OR
Patient must have received this drug for this condition prior to 1 January 2016, AND
The treatment must in combination with glucocorticoids, AND
Patient must be at risk of end-organ damage or mortality, AND
Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.
Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.
This drug is not PBS-subsidised for maintenance of remission

Authority required
Severe active microscopic polyangiitis
Treatment Phase: Induction of remission
Clinical criteria:
The treatment must be for the induction of remission, AND
Patient must not have previously received this drug for this condition; OR
Patient must have received this drug for this condition prior to 1 January 2016, AND
The treatment must in combination with glucocorticoids, AND
Patient must be at risk of end-organ damage or mortality, AND
Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.
Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.
This drug is not PBS-subsidised for maintenance therapy.

Authority required
Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)
Treatment Phase: Re-induction of remission
Clinical criteria:
The treatment must be for the re-induction of remission, AND
Patient must have previously received and responded to this drug for this condition, AND
The treatment must in combination with glucocorticoids, AND
Patient must be at risk of end-organ damage or mortality, AND
Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.
Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.
This drug is not PBS-subsidised for maintenance of remission

Authority required
Severe active microscopic polyangiitis
Treatment Phase: Re-induction of remission
Clinical criteria:

The treatment must be for the re-induction of remission, AND
Patient must have previously received and responded to this drug for this condition, AND
The treatment must in combination with glucocorticoids, AND
Patient must be at risk of end-organ damage or mortality, AND
Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.
Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.
This drug is not PBS-subsidised for maintenance therapy.

rituximab 100 mg/10 mL injection, 2 x 10 mL vials

10583B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	796.88	Mabthera [RO]

rituximab 500 mg/50 mL injection, 50 mL vial

10576P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	1945.85	Mabthera [RO]

HSD (Private)

▪ IMMUNOSTIMULANTS

IMMUNOSTIMULANTS

Colony stimulating factors

▪ FILGRASTIM

Authority required
For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia

Authority required
Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy

Authority required
A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required
A patient with severe congenital neutropenia (absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, and in whom a bone marrow examination has shown evidence of maturational arrest of the neutrophil lineage)

Authority required
A patient with severe chronic neutropenia (absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, or evidence of neutrophil dysfunction, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))

Authority required
A patient with chronic cyclic neutropenia (absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))

Authority required
A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required
Mobilisation of peripheral blood progenitor cells, in a normal volunteer, for use in allogeneic transplantation

Authority required
A patient receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation

Authority required
A patient with a non-myeloid malignancy receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation

Authority required
A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required
A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage

and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required

A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP)

filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes

5830W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	11	..	*693.51	Nivestim [HH]

filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

1082Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	11	..	*1697.37	TevaGrastim [TB]

filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

6291D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	11	..	*1697.37	Neupogen [AN]

filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

9693E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	11	..	*1697.37	Nivestim [HH]

filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes

2747N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	4	11	..	*1697.37	Zarzio [SZ]

filgrastim 300 microgram/mL injection, 10 x 1 mL vials

6126K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	11	..	*1697.37	Neupogen [AN]

filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes

6292E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	11	..	*2692.69	Neupogen [AN]

filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes

9695G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	11	..	*2692.69	Nivestim [HH]

filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes

2733W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	11	..	*2692.69	Zarzio [SZ]

filgrastim 480 microgram/0.8 mL injection, 10 x 0.8 mL syringes

1113N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	11	..	*2692.69	TevaGrastim [TB]

filgrastim 480 microgram/1.6 mL injection, 10 x 1.6 mL vials

6127L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	11	..	*2692.69	Neupogen [AN]

HSD (Private)

▪ LENOGRASTIM

Authority required

Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for reinfusion into patients with non-myeloid malignancies who have had myeloablative or myelosuppressive therapy

Authority required

Mobilisation of peripheral blood progenitor cells, in normal volunteers, for use in allogeneic transplantation to facilitate harvest of such cells in healthy donors

Authority required

Patients with non-myeloid malignancies receiving marrow-ablative chemotherapy and subsequent peripheral blood progenitor cell or bone marrow transplantation

Authority required

Patients with breast cancer receiving standard dose adjuvant chemotherapy who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required

Patients receiving first-line chemotherapy for Hodgkin's disease who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin's disease

Authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in rhabdomyosarcoma

Authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Ewing's sarcoma

Authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours

Authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours

Authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma

Authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin's lymphoma (intermediate or high grade)

Authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in osteosarcoma

Authority required

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia

LENOGRASTIM Powder for injection 13,400,000 i.u. (105 micrograms) vial, 10

6337M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	11	..	*1019.65	Granocyte 13 [HH]

LENOGRASTIM Powder for injection 33,600,000 i.u. (263 micrograms) vial, 10

6338N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	11	..	*2485.77	Granocyte 34 [HH]

▪ PEGFILGRASTIM

Authority required

For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia

Authority required

A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required

A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required

A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required

A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required

A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma

Authority required

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP)

pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

6363X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	11	..	1875.68	Neulasta [AN]

Interferons

▪ INTERFERON ALFA-2A

Caution Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Authority required

Chronic Myeloid Leukaemia (CML)

Clinical criteria:

The condition must be Philadelphia chromosome positive.

interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe

6210W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	30	5	..	*890.13	Roferon-A [RO]

interferon alfa-2a 4.5 million units/0.5 mL injection, 0.5 mL syringe

6211X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	30	5	..	*1320.93	Roferon-A [RO]

interferon alfa-2a 6 million units/0.5 mL injection, 0.5 mL syringe

6212Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	30	5	..	*1744.83	Roferon-A [RO]

interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe

6213B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	30	5	..	*2594.13	Roferon-A [RO]

▪ INTERFERON ALFA-2B

Caution Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Authority required

Chronic Myeloid Leukaemia (CML)

Clinical criteria:

The condition must be Philadelphia chromosome positive.

Authority required

Malignant melanoma

Clinical criteria:

The treatment must be as adjunctive therapy to current standard care, AND

Patient must have undergone surgery, AND

The condition must include nodal involvement.

interferon alfa-2b 10 million units/mL injection, 5 x 1 mL vials

6246R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	3	5	..	*1461.96	Intron A [MK]

interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL cartridge

6253D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*360.11	Intron A Redipen [MK]

interferon alfa-2b 18 million units/3 mL injection, 3 mL vial

6218G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	15	5	..	*2593.98	Intron A [MK]

interferon alfa-2b 25 million units/2.5 mL injection, 2.5 mL vial

6219H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	15	5	..	*3584.58	Intron A [MK]

interferon alfa-2b 30 million units/1.2 mL injection, 1.2 mL cartridge

6254E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*595.59	Intron A Redipen [MK]

interferon alfa-2b 60 million units/1.2 mL injection, 1.2 mL cartridge

6255F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1178.95	Intron A Redipen [MK]

▪ INTERFERON GAMMA-1B

Authority required

Treatment of chronic granulomatous disease in patients with frequent and severe infections despite adequate prophylaxis with antimicrobial agents

interferon gamma-1b 2 million units (100 microgram)/0.5 mL injection, 6 x 0.5 mL vials

6148N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	11	..	*2632.65	Imukin [BY]

▪ PEGINTERFERON ALFA-2A

Caution Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Note Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

Authority required

Chronic hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease, AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND

Patient must have a contraindication to ribavirin, AND

The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND

The treatment must be limited to a maximum duration of 48 weeks.

Population criteria:

Patient must be aged 18 years or older, AND

Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes

6439X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	..	*2262.15	Pegasys [RO]

peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes

6449K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	..	*2612.37	Pegasys [RO]

▪ PEGINTERFERON ALFA-2A (&) RIBAVIRIN

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 12 weeks.

Population criteria:

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [140 tablets], 1 pack

10674T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	..	1602.33	Pegasys RBV [RO]

peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack

10662E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	..	1682.60	Pegasys RBV [RO]

▪ PEGINTERFERON ALFA-2A (&) RIBAVIRIN

Caution Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

Authority required

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease, AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated), AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simeprevir, AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease, AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and in whom plasma HCV RNA is undetectable by an HCV RNA quantitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Chronic non-genotype 1 hepatitis C infection

Clinical criteria:

The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND
Patient must have compensated liver disease, AND
The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C, AND
Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated), AND
Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C, AND
The treatment must be limited to a maximum duration of 48 weeks, AND
The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.
Population criteria:
Patient must be aged 18 years or older, AND
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.
Treatment criteria:
Must be treated in an accredited treatment centre.
Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Chronic non-genotype 1 hepatitis C infection
Clinical criteria:
The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND
Patient must have compensated liver disease, AND
Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND
The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C, AND
The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR
The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR
The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis, AND
The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND
The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.
Population criteria:
Patient must be aged 18 years or older, AND
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.
Treatment criteria:
Must be treated in an accredited treatment centre.
Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.
For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.
For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.
For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.
For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.

peginterferon alfa-2a 135 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack

6392K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*3003.19	Pegasys RBV [RO]

peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [112 tablets], 1 pack

6394M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*2997.19	Pegasys RBV [RO]

peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [140 tablets], 1 pack

6395N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*3157.73	Pegasys RBV [RO]

peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack

6396P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	..	*3318.27	Pegasys RBV [RO]

▪ PEGINTERFERON ALFA-2B (&) RIBAVIRIN

Caution Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

HSD (Private)

Authority required

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease, AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated), AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simeprevir, AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease, AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and in whom plasma HCV RNA is undetectable by an HCV RNA quantitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Chronic non-genotype 1 hepatitis C infection

Clinical criteria:

The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND
Patient must have compensated liver disease, AND
The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C, AND
Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated), AND
Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C, AND
The treatment must be limited to a maximum duration of 48 weeks, AND
The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.
Population criteria:
Patient must be aged 18 years or older, AND
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.
Treatment criteria:
Must be treated in an accredited treatment centre.
Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Chronic non-genotype 1 hepatitis C infection
Clinical criteria:
The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND
Patient must have compensated liver disease, AND
Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND
The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C, AND
The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR
The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR
The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis, AND
The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND
The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.
Population criteria:
Patient must be aged 18 years or older, AND
Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.
Treatment criteria:
Must be treated in an accredited treatment centre.
Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.
For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.
For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.
For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.
For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.

peginterferon alfa-2b 120 microgram injection [4 x 120 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack

6407F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	..	*3538.51	Pegatron [MK]

peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack

6409H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	..	*4126.45	Pegatron [MK]

peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [168 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack

6410J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	..	*4126.45	Pegatron [MK]

peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [196 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack

9634C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*4411.41	Pegatron [MK]

peginterferon alfa-2b 80 microgram injection [4 x 80 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack

6402Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*2754.59	Pegatron [MK]

HSD (Private)

▪ PEGINTERFERON ALFA-2B (&) RIBAVIRIN

Caution Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

Authority required

Chronic genotype 1 hepatitis C infection

Clinical criteria:

The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND

Patient must have compensated liver disease, AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated), AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C, AND

The treatment must be limited to a maximum duration of 48 weeks, AND

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

Population criteria:

Patient must weigh at least 27 kg, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Chronic genotype 1 hepatitis C infection

Clinical criteria:

The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND

Patient must have compensated liver disease, AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND

The treatment must be limited to a maximum duration of 48 weeks, AND

The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop.

Population criteria:

Patient must weigh at least 27 kg, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Chronic non-genotype 1 hepatitis C infection

Clinical criteria:

The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND

Patient must have compensated liver disease, AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C, AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated), AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C, AND

The treatment must be limited to a maximum duration of 48 weeks, AND

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

Population criteria:

Patient must weigh at least 27 kg, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Chronic non-genotype 1 hepatitis C infection

Clinical criteria:

The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND

Patient must have compensated liver disease, AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C, AND

The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis, AND

The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND

The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must weigh at least 27 kg, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.

For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.

For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.

Authority required

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease, AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated), AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simeprevir, AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease, AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and in whom plasma HCV RNA is undetectable by an HCV RNA quantitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Chronic non-genotype 1 hepatitis C infection

Clinical criteria:

The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND

Patient must have compensated liver disease, AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C, AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated), AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C, AND

The treatment must be limited to a maximum duration of 48 weeks, AND

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

Population criteria:

Patient must be aged 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Chronic non-genotype 1 hepatitis C infection

Clinical criteria:

The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND

Patient must have compensated liver disease, AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C, AND

The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis, AND

The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND

The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.

For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.

For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.

peginterferon alfa-2b 100 microgram injection [4 x 100 microgram cartridges] (&) ribavirin 200 mg capsule [112 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack

6405D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*3146.55	Pegatron [MK]

peginterferon alfa-2b 50 microgram injection [4 x 50 microgram cartridges] (&) ribavirin 200 mg capsule [112 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack

6400W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*2166.67	Pegatron [MK]

peginterferon alfa-2b 80 microgram injection [4 x 80 microgram cartridges] (&) ribavirin 200 mg capsule [84 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack

6401X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*2469.65	Pegatron [MK]

Other immunostimulants

▪ PLERIXAFOR

Note Applications for increased maximum quantities will only be authorised for patients with body weight greater than 100 kg.

Authority required

Mobilisation of haematopoietic stem cells

Clinical criteria:

The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF), AND

Patient must have lymphoma; OR

Patient must have multiple myeloma, AND

Patient must require autologous stem cell transplantation, AND

Patient must have failed previous stem cell collection; OR

Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; OR

Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

plerixafor 24 mg/1.2 mL injection: subcutaneous infusion, 1.2 mL vial

10084R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	1	..	7037.93	Mozobil [GZ]

▪ IMMUNOSUPPRESSANTS

IMMUNOSUPPRESSANTS

Selective immunosuppressants

▪ ABATACEPT

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis, AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND

Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

Patient must not receive more than 16 weeks of treatment under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient

will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND

Patient must not receive more than 16 weeks of treatment under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:

- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing)

with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have demonstrated an adequate response to treatment with this drug, AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.

Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the

approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

abatacept 250 mg injection, 1 vial

9621J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	380.72	Orencia [BQ]

▪ ALEMTUZUMAB

Note Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.
Note Special Pricing Arrangements apply.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required

Multiple sclerosis

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug, AND

Patient must not show continuing progression of disability while on treatment with this drug, AND

Patient must not receive more than one PBS-subsidised treatment per year, AND

The treatment must be as monotherapy, AND

Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

Treatment criteria:

Must be treated by a neurologist.

alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial

10246G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
3	..	..	*34228.92	Lemtrada [GZ]

▪ ALEMTUZUMAB

Note Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.
Note Special Pricing Arrangements apply.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required

Multiple sclerosis

Treatment Phase: Initial

Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND

The treatment must be as monotherapy, AND

Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, AND

Patient must be ambulatory (without assistance or support).

Treatment criteria:

Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.

alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial

10243D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
5	..	..	*57016.93	Lemtrada [GZ]

▪ ECULIZUMAB

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 4 repeats, according to the specified dosage in the approved Product Information (PI).

Note Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment – Balance of Supply

Clinical criteria:

Patient must have received PBS-subsidised initial supply of eculizumab for this condition, AND

Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample, AND

Patient must not receive more than 20 weeks supply under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

ADAMTS-13 activity result must have been submitted to the Department of Human Services. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for Initial Treatment, ADAMTS-13 activity must have been measured 1-2 weeks following the last plasma exchange or infusion, and must have been submitted to the Department of Human Services within 27 days of commencement of eculizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the two weeks prior to collection of the ADAMTS-13 assay must also have been provided to Department of Human Services.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

eculizumab 300 mg/30 mL injection, 30 mL vial

10192K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	4	..	5984.43	Soliris [XI]

▪ ECULIZUMAB

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment, according to the specified dosage in the approved Product Information (PI)

Note Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)
> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use
> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination.
Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have active and progressing thrombotic microangiopathy (TMA), AND

Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than 30x10^9/L and a serum creatinine of greater than 150 mol/L, AND

Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days, AND

Patient must have clinical features of active organ damage or impairment, AND

Patient must not receive more than 4 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Evidence of active and progressing TMA is defined by the following:

(1) a platelet count of less than 150x10^9/L; and evidence of two of the following:

(i) presence of schistocytes on blood film;

(ii) low or absent haptoglobin;

(iii) lactate dehydrogenase (LDH) above normal range;

OR

(2) tissue biopsy confirming TMA in patients who do not have evidence of platelet consumption and haemolysis; AND

(3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one of the following:

(i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or

(ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or

(iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or

(iv) a renal biopsy

(b) onset of TMA-related neurological impairment;

(c) onset of TMA-related cardiac impairment;

(d) onset of TMA-related gastrointestinal impairment;

(e) onset of TMA-related pulmonary impairment

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form - Initial PBS-subsidised eculizumab treatment; and

(3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and

(4) A copy of a current Certificate of vaccination; and

(5) A measurement of body weight at the time of application; and

(6) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay; and

(7) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 1-2 weeks following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to the Department of Human Services within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under Initial treatment - balance of supply; and

(8) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days; and

(9) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within one month of application; and

(10) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.

eculizumab 300 mg/30 mL injection, 30 mL vial

10182X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	5984.43	Soliris [XI]

▪ ECULIZUMAB

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 6 repeats, according to the specified dosage in the approved Product Information (PI).

Note Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)
> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use
> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination.
Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Note For patients who have received continuing treatment with PBS-subsidised eculizumab prior to 1 January 2016, this restriction is limited to 28 weeks of therapy.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended initial treatment - Assessment phase

Clinical criteria:

Patient must have received treatment under the initial restriction with PBS subsidised eculizumab for this condition, AND

Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, AND

Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, AND

Patient must not receive more than 56 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure .

A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

A maximum of up to 56 weeks of treatment is allowed under this restriction, however an application must be submitted at 6 months, 12 months, 18 months and 24 months following commencing PBS-subsidised eculizumab.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Extended Initial treatment; and

(3) A copy of a current Certificate of vaccination; and

(4) A measurement of body weight at the time of application; and

(5) An identified genetic mutation, if applicable; and

(6) A family history of aHUS, if applicable; and

(7) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and

(8) A history of kidney transplant, if applicable, (especially if required due to aHUS); and

(9) An inclusion of the individual consequences of recurrent disease, if applicable; and

(10) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and

(11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(12) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

eculizumab 300 mg/30 mL injection, 30 mL vial

10521R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	6	..	5984.43	Soliris [XI]

▪ ECULIZUMAB

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)
> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use
> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have received treatment under Extended Initial restriction with PBS subsidised eculizumab for this condition, AND

Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, AND

Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, AND

Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure .

A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and

(3) A copy of a current Certificate of vaccination; and

(4) A measurement of body weight at the time of application; and

(5) An identified genetic mutation, if applicable; and

(6) A family history of aHUS, if applicable; and

(7) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and

(8) A history of kidney transplant if applicable (especially if required due to aHUS); and

(9) An inclusion of the individual consequences of recurrent disease, if applicable; and

(10) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and

(11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(12) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Note Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended Continuing treatment

Clinical criteria:

Patient must have received treatment under the Continuing treatment with PBS-subsidised eculizumab for this condition, AND

Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition, AND

Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, AND

Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40%; OR

Patient must have severe TMA-related neurological impairment; OR

Patient must have severe TMA-related gastrointestinal impairment; OR

Patient must have severe TMA-related pulmonary impairment; OR

Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 ml/min), AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure . A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and

(3) A copy of a current Certificate of vaccination; and

(4) A measurement of body weight at the time of application; and

(5) An identified genetic mutation, if applicable; and

(6) A family history of aHUS, if applicable; and

(7) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and

(8) A history of kidney transplant, if applicable (especially if required due to aHUS); and

(9) An inclusion of the individual consequences of recurrent disease; and

(10) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment; and

(11) Evidence that the patient has had a treatment response including haematological results of no more than 1 month old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 month old at the time of application; and

(12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Note Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have demonstrated treatment response to previous treatment with PBS-subsidised eculizumab for this condition, AND

Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, AND

Patient must have the following clinical conditions:(i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal;AND(ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count <150 x 10^9/L);OR(iii) TMA-related organ impairment including on recent biopsy, AND

Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure . A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form(s); and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Recommencement of treatment; and

(3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and

(4) A copy of a current Certificate of vaccination; and

(5) A measurement of body weight at the time of application, and

(6) An identified genetic mutation, if applicable; and

(7) A family history of aHUS if applicable; and

(8) A history of multiple episodes of aHUS following the treatment break, if applicable; and

(9) A history of kidney transplant if applicable (especially if required due to aHUS); and

(10) An inclusion of the individual consequences of recurrent disease; and

(11) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;

(12) Evidence that the patient has had a treatment response to their previous treatment with eculizumab; and

(13) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(14) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Note Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note A raise in LDH alone is not a sufficient reason to re-commence eculizumab, but thrombocytopenia with one marker of haemolysis (such as raised LDH, presence of schistocytes, or low/absence of haptoglobin) is an accepted reason to consider re-commencement of eculizumab treatment.

Note Kidney transplantation/dialysis is not a contraindication to recommencement of eculizumab treatment.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing recommencement of treatment

Clinical criteria:

Patient must have received treatment under Recommencement of treatment restriction with PBS-subsidised eculizumab for this condition, AND

Patient must have demonstrated ongoing treatment response to the previous 24 weeks of PBS-subsidised eculizumab for this condition, AND

Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, AND

Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure . A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and

(3) A copy of a current Certificate of vaccination; and

(4) A measurement of body weight at the time of application; and

(5) An identified genetic mutation, if applicable; and

(6) A family history of aHUS, if applicable; and

(7) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and

(8) A history of kidney transplant if applicable (especially if required due to aHUS); and

(9) An inclusion of the individual consequences of recurrent disease, if applicable; and

(10) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and

(11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(12) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Note Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Grandfather eculizumab patient

Clinical criteria:

Patient must have had documented history of active and progressing thrombotic microangiopathy (TMA), AND

Patient must have had documented an ADAMTS-13 activity level consistent with a diagnosis of aHUS, AND

Patient must have received treatment with eculizumab for this condition prior to 1 December 2014, AND

Patient must have received treatment with eculizumab within the last 6 months at the time of application, AND

Patient must have demonstrated on-going treatment response as specified in the Extended Initial treatment criteria for PBS-subsidised treatment with eculizumab for this condition, if the patient has received adequate therapy in order to demonstrate response, AND

Patient must not have experienced treatment failure with eculizumab for this condition as specified in the Extended Initial treatment criteria for PBS-subsidised treatment with eculizumab for this condition, AND

Patient must have clinical features of active organ damage or impairment at the time of a diagnosis of aHUS episode that required treatment with eculizumab, AND

Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Evidence of active and progressing TMA is defined by the following:

(1) a platelet count of less than 150x10^9/L; and evidence of two of the following:

(i) presence of schistocytes on blood film;

(ii) low or absent haptoglobin;

(iii) lactate dehydrogenase (LDH) above normal range;

OR

(2) tissue biopsy confirming TMA in patients who do not have evidence of platelet consumption and haemolysis; AND

(3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one of the following:

(i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or

(ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or

(iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or

(iv) a renal biopsy

(b) onset of TMA-related neurological impairment;

(c) onset of TMA-related cardiac impairment;

(d) onset of TMA-related gastrointestinal impairment;

(e) onset of TMA-related pulmonary impairment

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure . A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for initial PBS-subsidised eculizumab treatment; and

(3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and

(4) A copy of a current Certificate of vaccination; and

(5) A measurement of body weight at the time of application; and

(6) The result of ADAMTS-13 activity on a blood sample at the time this condition was diagnosed; and

(7) An identified genetic mutation, if applicable; and

(8) A family history of aHUS, if applicable; and

(9) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and

(10) A history of kidney transplant if applicable (especially if required due to aHUS); and

(11) An inclusion of the individual consequences of recurrent disease; and

(12) Evidence that the patient has previously received treatment with eculizumab for this condition within the last 6 months at the time of application; and

(13) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; or clinical reasons to justify the commencing of treatment with PBS-subsidised eculizumab; and

(14) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(15) A confirmed negative STEC (Shiga toxin-producing E.Coli) result if available at the time of diagnosis; or evidence that the diagnosis was not associated with an infection; and

(16) Where available in the week prior to commencing eculizumab results demonstrating:

(a) a platelet count of less than 150 x10^9/L; and evidence of two of the following:
(i) presence of schistocytes on blood film;
(ii) low or absent haptoglobin;
(iii) lactate dehydrogenase (LDH) above normal range;
OR
(b) tissue biopsy confirming TMA in patients who do not have evidence of platelet consumption and haemolysis; AND
(c) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:
(a) kidney impairment as demonstrated by one of the following:
(i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or
(ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or
(iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or
(iv) a renal biopsy
(b) onset of TMA-related neurological impairment;
(c) onset of TMA-related cardiac impairment;
(d) onset of TMA-related gastrointestinal impairment;
(e) onset of TMA-related pulmonary impairment; and
(17) Where available within one month prior to commencement of eculizumab, evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records.
This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

eculizumab 300 mg/30 mL injection, 30 mL vial

10194M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	5984.43	Soliris [XI]

▪ EVEROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority required
Management of renal allograft rejection
Treatment Phase: Management (initiation, stabilisation and review of therapy)
Clinical criteria:
Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND
The treatment must be under the supervision and direction of a transplant unit.

Authority required
Management of cardiac allograft rejection
Treatment Phase: Management (initiation, stabilisation and review of therapy)
Clinical criteria:
Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, AND
The treatment must be under the supervision and direction of a transplant unit.

everolimus 1 mg tablet, 60

9582H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	5	..	*3699.49	Certican [NV]

everolimus 250 microgram tablet, 60

6459Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	..	*481.77	Certican [NV]

everolimus 500 microgram tablet, 60

6460B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	..	*956.59	Certican [NV]

everolimus 750 microgram tablet, 60

6461C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	5	..	*2786.37	Certican [NV]

▪ MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Authority required
Management of renal allograft rejection
Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:
Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND
The treatment must be under the supervision and direction of a transplant unit.

Authority required
Management of cardiac allograft rejection
Treatment Phase: Management (initiation, stabilisation and review of therapy)
Clinical criteria:
Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, AND
The treatment must be under the supervision and direction of a transplant unit.

mycophenolate mofetil 1 g/5 mL oral liquid: powder for, 165 mL

6364Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	..	*#518.16	CellCept [RO]

mycophenolate mofetil 500 mg tablet, 50

6209T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
6	5	..	*452.97	[a] APO-Mycophenolate [TX]	[a] CellCept [RO]
				[a] Ceptolate [AF]	[a] Mycophenolate AN [EA]
				[a] Mycophenolate Sandoz [SZ]	[a] Pharmacor Mycophenolate 500 [CR]

▪ MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Note Management includes initiation, stabilisation and review of therapy as required.

Authority required
Prophylaxis of renal allograft rejection
Treatment Phase: Management
Clinical criteria:
The treatment must be under the supervision and direction of a transplant unit.

Authority required
WHO Class III, IV or V lupus nephritis
Treatment Phase: Management
Clinical criteria:
The condition must be proven by biopsy.
Treatment criteria:
Must be treated by a nephrologist or in consultation with a nephrologist.
The name of the consulting nephrologist must be included in the patient medical records.

mycophenolate 180 mg tablet: enteric, 120

6369F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	..	*185.37	Myfortic [NV]

mycophenolate 360 mg tablet: enteric, 120

6370G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	..	*363.77	Myfortic [NV]

▪ MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Note For item codes 6208R and 1837Q, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution.

Authority required
Management of renal allograft rejection
Treatment Phase: Management (initiation, stabilisation and review of therapy)
Clinical criteria:
Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND
The treatment must be under the supervision and direction of a transplant unit.

Authority required
Management of cardiac allograft rejection
Treatment Phase: Management (initiation, stabilisation and review of therapy)
Clinical criteria:
Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, AND
The treatment must be under the supervision and direction of a transplant unit.

mycophenolate Capsule 250 mg, 50

1837Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
12	5	..	*453.09	[a] Ceptolate [AF]

mycophenolate mofetil 250 mg capsule, 100

6208R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*453.09	[a] APO-Mycophenolate [TX] [a] Mycophenolate Sandoz [SZ]	[a] CellCept [RO] [a] Pharmacor Mycophenolate 250 [CR]

▪ NATALIZUMAB

Caution Progressive multifocal leukoencephalopathy has been reported with this drug.

Authority required

Clinically definite relapsing-remitting multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

The treatment must be as monotherapy, AND

Patient must be ambulatory (without assistance or support), AND

Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years, AND

The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; OR

Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a neurologist.

The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.

Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

Authority required

Clinically definite relapsing-remitting multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

The treatment must be as monotherapy, AND

Patient must have previously been issued with an authority prescription for this drug, AND

Patient must not show continuing progression of disability while on treatment with this drug, AND

Patient must have demonstrated compliance with, and an ability to tolerate, this therapy.

Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

natalizumab 300 mg/15 mL injection, 15 mL vial

9624M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	..	1536.57	Tysabri [BD]

▪ SIROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority required

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND

The treatment must be under the supervision and direction of a transplant unit.

sirolimus 1 mg tablet, 100

6436R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1421.25	Rapamune [PF]

sirolimus 1 mg/mL oral liquid, 60 mL

6437T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*931.69	Rapamune [PF]

sirolimus 2 mg tablet, 100

6457W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*2795.61	Rapamune [PF]

sirolimus 500 microgram tablet, 100

9748C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*721.59	Rapamune [PF]

▪ VEDOLIZUMAB

Note Special Pricing Arrangements apply.

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of infliximab and vedolizumab for adult patients with ulcerative colitis.

Patients are eligible for PBS-subsidised treatment with either infliximab or vedolizumab at any one time.

From 1 August 2015, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised infliximab or vedolizumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with infliximab or vedolizumab while they continue to show a response to therapy.

A patient who received PBS-subsidised infliximab or vedolizumab treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised infliximab or vedolizumab more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised infliximab or vedolizumab treatment in the most recent cycle to the date of the first application for initial treatment with infliximab or vedolizumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of either infliximab or vedolizumab in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of either infliximab or vedolizumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

(1) How to prescribe PBS-subsidised infliximab or vedolizumab therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised treatment with infliximab or vedolizumab in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) infliximab or vedolizumab therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with infliximab or vedolizumab following a break in PBS-subsidised therapy with the same agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 14 weeks of therapy.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised treatment up to 12 weeks after the first dose (6 weeks following the third dose), and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

For second and subsequent courses of PBS-subsidised infliximab or vedolizumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with infliximab or vedolizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate infliximab or vedolizumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with infliximab or vedolizumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate infliximab or vedolizumab therapy should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Mayo clinic score or partial Mayo clinic score submitted with the first authority application for infliximab or vedolizumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised infliximab or vedolizumab therapy of at least 5 years, must requalify for initial treatment with respect to the scores of disease severity.
Patients must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine, 6-mercaptopurine or tapered course of oral steroids (unless intolerance develops necessitating permanent treatment withdrawal) for a minimum of 3 consecutive months immediately prior to the time the Mayo score or PUCAI score is measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab or infliximab.
A patient who commenced treatment with vedolizumab for moderate to severe ulcerative colitis prior to 1 August 2015 or infliximab prior to 1 December 2014 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment (new patient – Initial 1)

Clinical criteria:

Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal, AND

Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR

Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR

Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, AND

Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR

Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), AND

Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 1 month old at the time of application.

Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose for patients administered doses at weeks 0, 2 and 6 (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

Patients must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Note Details of accepted toxicities including severity can be found on the Department of Human Services website at www.humanservices.gov.au.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug for this condition, AND

Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug, AND

Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

Note No applications for increased repeats will be authorised.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial PBS-subsidised treatment (Grandfather patient)

Clinical criteria:

Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 August 2015, AND

Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing treatment with this drug; OR

Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing treatment with this drug; OR

Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing treatment with this drug; OR

Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing treatment with this drug; OR

Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced treatment with this drug where a Mayo clinic or partial Mayo clinic baseline assessment is not available; OR

Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced treatment with this drug where a Mayo clinic or partial Mayo clinic baseline assessment is not available, AND

Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug, AND

Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

Patient must be 18 years of age or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and baseline Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the date of commencement of this drug; and

(iii) the signed patient acknowledgement.

The current Mayo clinic or partial Mayo clinic assessment must be no more than 1 month old at the time of application. The baseline assessment must be from immediately prior to commencing treatment with this drug. Where a baseline assessment is not available the prescriber must contact the Department of Human Services to discuss.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note The patient must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

Note No applications for increased repeats will be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Change or Re-commencement of treatment after a break in therapy (Initial 2)

Clinical criteria:

Patient must have previously been issued with an authority prescription for infliximab or vedolizumab for this condition in this treatment cycle, AND

Patient must not have failed PBS-subsidised therapy with vedolizumab for this condition more than once in the current treatment cycle, AND

Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses of treatment may be requested by telephone by contacting the Department of Human Services.

Note No applications for increased repeats will be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR

Patient must have received insufficient therapy with this drug to complete 24 weeks of treatment under the Initial PBS-subsidised treatment restriction for patients who had previously received non-PBS subsidised treatment (Grandfathered patient), AND

The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing or Grandfathered patients), AND

Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

Note Written applications for authority approval for sufficient therapy to complete the balance of supply should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

vedolizumab 300 mg injection, 1 x 300 mg vial

10398G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	3152.12	Entyvio [TK]

▪ VEDOLIZUMAB

Note No applications for increased maximum quantities will be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Special Pricing Arrangements apply.

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab).
Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.
From 1 August 2015, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised TNF-alfa antagonist or vedolizumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist or vedolizumab while they continue to show a response to therapy.
A patient who received PBS-subsidised TNF-alfa antagonist or vedolizumab treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist or vedolizumab more than twice.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist or vedolizumab treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist or vedolizumab under the new treatment cycle.
A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised TNF-alfa antagonist or vedolizumab therapy after 1 August 2015.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised therapy with TNF-alfa antagonist or vedolizumab in this treatment cycle

and wishes to commence such therapy (new patients); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy or vedolizumab and wishes to trial an alternate agent (recommencement) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist or vedolizumab following a break in PBS-subsidised therapy with that agent (change or re-commencement).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab and 14 weeks of therapy for vedolizumab.
From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.
For second and subsequent courses of PBS-subsidised TNF-alfa antagonist or vedolizumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific TNF-alfa antagonist or vedolizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist or vedolizumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist or vedolizumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist or vedolizumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist or vedolizumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.
A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment (new patient – initial 1)

Clinical criteria:

Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, AND

Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR

Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, AND

Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR

Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR

Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug, AND

Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment, AND

Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR

Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, AND

Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR

Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR

Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply

restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

Note This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Authority required

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

Clinical criteria:

Patient must have a documented history of severe Crohn disease, AND

Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, AND

Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle, AND

Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Authority required

Severe Crohn disease

Treatment Phase: Initial PBS-subsidised treatment (Grandfather)

Clinical criteria:

Patient must have a documented history of severe Crohn disease, AND

Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 August 2015, AND

Patient must have had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with this drug; OR

Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR

Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, AND

Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR

Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, AND

Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR

Patient must have received insufficient therapy with this drug to complete 24 weeks of treatment under the Initial PBS-subsidised treatment restriction for patients who had previously received non-PBS subsidised treatment (Grandfathered patient), AND

The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing or Grandfathered patients), AND

Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Note Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe Crohn disease, AND

Patient must have previously been issued with an authority prescription for this drug for this condition, AND

Patient must have demonstrated or sustained an adequate response to treatment with this drug, AND

Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment, AND

Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR

Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests and diagnostic imaging studies, must be made within 1 month of the date of application.

If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

vedolizumab 300 mg injection, 1 x 300 mg vial

10415E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	3152.12	Entyvio [TK]

Tumor necrosis factor alpha (TNF-) inhibitors

▪ ADALIMUMAB

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

Clinical criteria:

Patient must have severe active juvenile idiopathic arthritis, AND

Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR

Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, AND

Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR

Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis, AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, AND

Patient must not have failed PBS-subsidised therapy with adalimumab for this condition in the current treatment cycle, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

Clinical criteria:

Patient must have received insufficient adalimumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient adalimumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis, AND

Patient must have demonstrated an adequate response to treatment with adalimumab, AND

Patient must have received adalimumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
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Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to

have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:

Patient must have received insufficient adalimumab therapy under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes

9678J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	1595.43	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

9680L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	1595.43	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9679K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	1595.43	Humira [VE]

▪ ETANERCEPT

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

Clinical criteria:

Patient must have severe active juvenile idiopathic arthritis, AND

Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR

Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, AND

Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR

Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis, AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, AND

Patient must not have failed PBS-subsidised therapy with etanercept for this condition in the current treatment cycle, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

Clinical criteria:

Patient must have received insufficient etanercept therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient etanercept therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis, AND

Patient must have demonstrated an adequate response to treatment with etanercept, AND

Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24

weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:

Patient must have received insufficient etanercept therapy under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

9641K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	1595.44	Enbrel [PF]

ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

9615C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	1595.44	Enbrel [PF]

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

6367D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	812.15	Enbrel [PF]

▪ INFLIXIMAB

Note No increase in the maximum number of repeats may be authorised.

Authority required

Acute severe ulcerative colitis

Clinical criteria:

Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application, AND

Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; OR

Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below, AND

Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital.

Population criteria:

Patient must be 6 years of age or older.

Treatment criteria:

Must be treated by a gastroenterologist; OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology].

For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where:

(i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L

(ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood.

For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours.

At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient's medical records.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

infliximab 100 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
10057H	1	1	..	604.77	[a] Inflectra [HH]	[a] Remicade [JC]

▪ INFLIXIMAB

Note Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe infliximab should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.
For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.
Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.
A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.
(3) Baseline measurements to determine response.
Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.
A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Initial 1

Initial treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has an externally draining enterocutaneous or rectovaginal fistula; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6 will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Authority required

Initial 2

Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and

(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Authority required

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

(a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with infliximab prior to 1 March 2010; and

(b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with infliximab; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) is receiving treatment with infliximab at the time of application; and

(e) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with infliximab.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

Authority required

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

infliximab 100 mg injection, 1 vial

9674E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	604.77	[a] Inflectra [HH]	[a] Remicade [JC]

HSD (Private)

▪ INFLIXIMAB

Note Special Pricing Arrangements apply.

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time.

For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab.

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to theDepartment of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure

uninterrupted TNF-alfa antagonist supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient with severe disease may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).
A patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PCDAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.
Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.
A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

Authority required

Moderate to severe Crohn disease

Treatment Phase: Initial treatment (new paediatric patient) of Crohn disease in a paediatric patient assessed by PCDAI (Initial 1)

Clinical criteria:

Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, AND

Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR

Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, AND

Patient must have, at the time of application, disease severity considered to be moderate to severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment and which is no more than 1 month old at the time of application.

Population criteria:

Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician or a specialist paediatric gastroenterologist; OR

Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription forms; and

(b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition; and

(iii) the signed patient or guardian acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Human Services website (www.humanservices.gov.au).

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe Crohn disease

Treatment Phase: Change or re-commencement of treatment of Crohn disease in a paediatric patient assessed by PCDAI (Initial 2)

Clinical criteria:

Patient must have a documented history of moderate to severe Crohn disease, AND

Patient must in this treatment cycle, have received prior PBS-subsidised treatment with this drug for this condition; OR

Patient must in this treatment cycle, have received prior PBS-subsidised treatment with adalimumab for this condition, AND

Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

Population criteria:

Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician or a specialist paediatric gastroenterologist; OR

Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and

(ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe Crohn disease

Treatment Phase: Continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

Clinical criteria:

Patient must have a documented history of moderate to severe Crohn disease, AND

Patient must have previously been issued with an authority prescription for this drug for this condition, AND

Patient must have demonstrated an adequate response to treatment with this drug as defined as a reduction in PCDAI Score by at least 15 points as compared to baseline and a total of PCDAI score of 30 points or less with the PCDAI assessment being no more than 1 month old at the time of application.

Population criteria:

Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician or a specialist paediatric gastroenterologist; OR

Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:

(i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with this drug, a PCDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the 'Balance of Supply' treatment phase PBS restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe Crohn disease

Treatment Phase: Balance of supply for a paediatric patient

Clinical criteria:

Patient must have received insufficient therapy with this drug under Initial 1 (new patient or patient recommencing treatment after break of more than 5 years) or Initial 2 (change or recommencement of treatment after a break of less than 5 years) or Continuing treatment to complete the maximum duration of treatment specified in the relevant treatment phase, AND

The treatment must provide no more than the balance of up to 3 doses or 2 repeats.

Treatment criteria:

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician or a specialist paediatric gastroenterologist; OR

Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

Note Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

infliximab 100 mg injection, 1 vial

9612X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	604.77	[a] Inflectra [HH]	[a] Remicade [JC]

▪ INFLIXIMAB

Note No applications for increased maximum quantities will be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Special Pricing Arrangements apply.

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab).
Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.

From 1 August 2015, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised TNF-alfa antagonist or vedolizumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist or vedolizumab while they continue to show a response to therapy.
A patient who received PBS-subsidised TNF-alfa antagonist or vedolizumab treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist or vedolizumab more than twice.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist or vedolizumab treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist or vedolizumab under the new treatment cycle.
A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised TNF-alfa antagonist or vedolizumab therapy after 1 August 2015.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised therapy with TNF-alfa antagonist or vedolizumab in this treatment cycle and wishes to commence such therapy (new patients); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy or vedolizumab and wishes to trial an alternate agent (recommencement) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist or vedolizumab following a break in PBS-subsidised therapy with that agent (change or re-commencement).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab and 14 weeks of therapy for vedolizumab.
From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.
For second and subsequent courses of PBS-subsidised TNF-alfa antagonist or vedolizumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific TNF-alfa antagonist or vedolizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist or vedolizumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist or vedolizumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist or vedolizumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist or vedolizumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess

response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.
A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment (new patient - initial 1)

Clinical criteria:

Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, AND

Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR

Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, AND

Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR

Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR

Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug, AND

Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR

Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, AND

Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR

Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR

Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Authority required

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

Clinical criteria:

Patient must have a documented history of severe Crohn disease, AND

Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, AND

Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction.

Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, AND

The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing treatment).

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

Authority required

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe Crohn disease, AND

Patient must have previously been issued with an authority prescription for this drug for this condition, AND

Patient must have demonstrated or sustained an adequate response to treatment with this drug, AND

Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR

Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

Up to a maximum of 2 repeats will be authorised.

infliximab 100 mg injection, 1 vial

9613Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	604.77	[a] Inflectra [HH]	[a] Remicade [JC]

HSD (Private)

▪ INFLIXIMAB

Note Special Pricing Arrangements apply.

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of infliximab and vedolizumab for adult patients with ulcerative colitis.

Patients are eligible for PBS-subsidised treatment with either infliximab or vedolizumab at any one time.

From 1 August 2015, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised infliximab or vedolizumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with infliximab or vedolizumab while they continue to show a response to therapy.

A patient who received PBS-subsidised infliximab or vedolizumab treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised infliximab or vedolizumab more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised infliximab or vedolizumab treatment in the most recent cycle to the date of the first application for initial treatment with infliximab or vedolizumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of either infliximab or vedolizumab in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of either infliximab or vedolizumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

(1) How to prescribe PBS-subsidised infliximab or vedolizumab therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised treatment with infliximab or vedolizumab in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) infliximab or vedolizumab therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with infliximab or vedolizumab following a break in PBS-subsidised therapy with the same agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 14 weeks of therapy.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised treatment up to 12 weeks after the first dose (6 weeks following the third dose), and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

For second and subsequent courses of PBS-subsidised infliximab or vedolizumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with infliximab or vedolizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate infliximab or vedolizumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with infliximab or vedolizumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to the alternate infliximab or vedolizumab therapy should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Mayo clinic score or partial Mayo clinic score submitted with the first authority application for infliximab or vedolizumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised infliximab or vedolizumab therapy of at least 5 years, must requalify for initial treatment with respect to the scores of disease severity.
Patients must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine, 6-mercaptopurine or tapered course of oral steroids (unless intolerance develops necessitating permanent treatment withdrawal) for a minimum of 3 consecutive months immediately prior to the time the Mayo score or PUCAI score is measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab or infliximab.
A patient who commenced treatment with vedolizumab for moderate to severe ulcerative colitis prior to 1 August 2015 or infliximab prior to 1 December 2014 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment (new patient - Initial 1)

Clinical criteria:

Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal, AND

Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR

Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR

Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, AND

Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR

Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR

Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years; OR

Patient must have previously received induction therapy with this drug for an acute severe episode of ulcerative colitis in the last 4 months and demonstrated an adequate response to induction therapy by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 (if aged 6 to 17 years).

Population criteria:

Patient must be 6 years of age or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician; OR

Must be treated by a specialist paediatric gastroenterologist.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 1 month old at the time of application.

Where treatment for an acute severe episode has occurred, an adequate response to induction therapy needs to be demonstrated by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 (if aged 6 to 17 years), within the first 12 weeks of receiving this drug for acute severe ulcerative colitis.

Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 within the first 12 weeks of receiving this drug for ulcerative colitis, or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or have failed to maintain a PUCAI score less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose for patients administered doses at weeks 0, 2 and 6 (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The patient or guardian (required if patient is aged 6 to 17 years) must have signed a patient acknowledgement indicating that he or she understands and acknowledges that the PBS-subsidised treatment will cease if he or she does not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug for this condition, AND

Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR

Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician; OR

Must be treated by a specialist paediatric gastroenterologist.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Up to a maximum of 2 repeats will be authorised.

Note No applications for increased repeats will be authorised.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial PBS-subsidised treatment (Grandfather patient)

Clinical criteria:

Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 December 2014, AND

Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing treatment with this drug; OR

Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing treatment with this drug; OR

Patient must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 prior to commencing treatment with this drug; OR

Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced treatment with this drug where a Mayo clinic, partial Mayo clinic or PUCAI baseline assessment is not available, AND

Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR

Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.

Population criteria:

Patient must be 6 years of age or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician; OR

Must be treated by a specialist paediatric gastroenterologist.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and baseline Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) the date of commencement of this drug; and

(iii) the signed patient acknowledgement.

The current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment must be no more than 1 month old at the time of application. The baseline assessment must be from immediately prior to commencing treatment with this drug. Where a baseline assessment is not available the prescriber must contact the Department of Human Services to discuss.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Up to a maximum of 2 repeats will be authorised.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note The patient or guardian (required if patient is aged 6 to 17 years) must have signed a patient acknowledgement indicating that he or she understands and acknowledges that the PBS-subsidised treatment will cease if he or she does not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

Note No applications for increased repeats will be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Change or Re-commencement of treatment after a break in therapy (Initial 2)

Clinical criteria:

Patient must have previously been issued with an authority prescription for infliximab or vedolizumab for this condition in this treatment cycle, AND

Patient must not have failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician; OR

Must be treated by a specialist paediatric gastroenterologist.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Up to a maximum of 2 repeats will be authorised.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

Note No applications for increased repeats will be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR

Patient must have received insufficient therapy with this drug to complete 24 weeks of treatment under the Initial PBS-subsidised treatment restriction for patients who had previously received non-PBS subsidised treatment (Grandfathered patient), AND

The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing or Grandfathered patients).

Population criteria:

Patient must be 6 years of age or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician; OR

Must be treated by a specialist paediatric gastroenterologist.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

Written applications for authority approval for sufficient therapy to complete balance of supply should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

infliximab 100 mg injection, 1 vial

10184B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	604.77	[a] Inflectra [HH]	[a] Remicade [JC]

▪ INFLIXIMAB

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis, AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND

Patient must have not failed previous PBS-subsidised treatment with infliximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

Patient must not receive more than 22 weeks of treatment under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application including severity.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be

submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND

Patient must not receive more than 22 weeks of treatment under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

If a patient fails to demonstrate a response to a treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
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Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a

disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient infliximab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 22 weeks treatment; OR

Patient must have received insufficient infliximab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 22 weeks treatment, AND

The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have demonstrated an adequate response to treatment with infliximab, AND

Patient must have received infliximab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats will be authorised.

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an

alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

Clinical criteria:

Patient must have received insufficient infliximab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

infliximab 100 mg injection, 1 vial

6397Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	604.77	[a] Inflectra [HH]	[a] Remicade [JC]

▪ INFLIXIMAB

Authority required

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, AND

Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab or infliximab in this treatment cycle, AND

Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, AND

Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 18 weeks of treatment with this drug will be approved under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

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Authority required

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis, AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, AND

Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, AND

Patient must be eligible to receive further bDMARD therapy.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 18 weeks of treatment with this drug will be approved under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.
Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.
From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.
A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is

submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

Clinical criteria:

Patient must have active, or a documented history of active, ankylosing spondylitis, AND

Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 18 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 18 weeks treatment, AND

The treatment must provide no more than the balance of up to 18 weeks treatment available under the above restrictions.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

Note Authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis, AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND

Patient must have demonstrated an adequate response to treatment with this drug.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.
Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.
From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.
A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis, AND

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

infliximab 100 mg injection, 1 vial

6448J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	604.77	[a] Inflectra [HH]	[a] Remicade [JC]

▪ INFLIXIMAB

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe active psoriatic arthritis, AND

Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, AND

Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, AND

Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR

Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, AND

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis, AND

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, AND

Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, AND

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or ustekinumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab for adult patients with severe active psoriatic arthritis.
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.
Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab only.
Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.
Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.
Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.
Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that

patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.
Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
Grandfather patients - ustekinumab only.
For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 22 weeks treatment, AND

The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be

forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis, AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND

Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
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Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab for adult patients with severe active psoriatic arthritis.
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.
Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab only.
Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.
Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.
Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.
Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.
Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
Grandfather patients - ustekinumab only.
For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

infliximab 100 mg injection, 1 vial

6496X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	604.77	[a] Inflectra [HH]	[a] Remicade [JC]

▪ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, secukinumab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, secukinumab and ustekinumab only.
Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.
Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.
Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.
Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Application for approval for initial treatment.
Applications for a course of initial treatment should be made in the following situations:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
(iii) patients who wish to recommence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab, etanercept and secukinumab, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.
Grandfather patients (secukinumab only).
Applications for patients who commenced treatment with secukinumab for chronic plaque psoriasis prior to 1 September 2015 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Application for continuing treatment.
Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.
For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
(4) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.
(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, AND

Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, AND

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at

least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, AND

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, AND

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, AND

Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, AND

Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, AND

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, AND

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, AND

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, AND

Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment) restriction to complete 22 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment) restriction to complete 22 weeks treatment, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND

Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND

Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, AND

The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

infliximab 100 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
9617E	1	..	..	604.77	[a] Inflectra [HH]	[a] Remicade [JC]

Interleukin inhibitors

▪ ANAKINRA

Note This drug is not PBS-subsidised for conditions other than CAPS.

Authority required (STREAMLINED)

5450

Moderate to severe cryopyrin associated periodic syndromes (CAPS)

Treatment criteria:

Must be treated by a rheumatologist or in consultation with a rheumatologist; OR

Must be treated by a rheumatologist or in consultation with a rheumatologist; OR

Must be treated by a clinical immunologist or in consultation with a clinical immunologist; OR

Must be treated by a clinical immunologist or in consultation with a clinical immunologist.

A diagnosis of CAPS must be documented in the patient's medical records.

anakinra 100 mg/0.67 mL injection, 28 x 0.67 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
10263E	1	5	..	1696.93	Kineret [FK]

▪ TOCILIZUMAB

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

Clinical criteria:

Patient must have severe active juvenile idiopathic arthritis, AND

Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR

Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, AND

Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR

Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis, AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, AND

Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks

of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis, AND

Patient must have demonstrated an adequate response to treatment with tocilizumab, AND

Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such

therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment – balance of supply

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

tocilizumab 200 mg/10 mL injection, 10 mL vial

10079L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	357.31	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

10060L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	704.03	Actemra [RO]

tocilizumab 80 mg/4 mL injection, 4 mL vial

10068X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	148.32	Actemra [RO]

HSD (Private)

▪ TOCILIZUMAB

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR

Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle, AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-

subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, AND

Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4

weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND

Patient must have demonstrated an adequate response to treatment with tocilizumab, AND

Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment – balance of supply

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

tocilizumab 200 mg/10 mL injection, 10 mL vial

10071C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	357.31	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

10078K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	704.03	Actemra [RO]

tocilizumab 80 mg/4 mL injection, 4 mL vial

10073E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	148.32	Actemra [RO]

▪ TOCILIZUMAB

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis, AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND

Patient must not have failed previous PBS-subsidised treatment with tocilizumab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-

subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment

applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) completed authority prescription form(s); and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to a treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term

bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient

will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have demonstrated an adequate response to treatment with tocilizumab, AND

Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is

sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.

Abatacept patients:

Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is

important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

tocilizumab 200 mg/10 mL injection, 10 mL vial

9672C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	357.31	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

9673D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	704.03	Actemra [RO]

tocilizumab 80 mg/4 mL injection, 4 mL vial

9671B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	148.32	Actemra [RO]

▪ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).
From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show a response to therapy, and
(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.
Once a patient has either failed or ceased to respond to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to receive further PBS-subsidised tocilizumab therapy. The length of a treatment break is measured from

the date the most recent treatment with PBS-subsidised tocilizumab treatment was stopped to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.
A patient who was receiving PBS-subsidised tocilizumab treatment immediately prior to 1 May 2012 is considered to be in their first cycle as of 1 May 2012. A patient who has had a break in tocilizumab treatment of at least 12 months immediately prior to making a new application, on or after 1 May 2012, will commence a new treatment cycle.
A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of less than 12 months may commence a second course of treatment within the same treatment cycle.
A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
(1) How to prescribe PBS-subsidised tocilizumab therapy after 1 May 2012.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised tocilizumab treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain a response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2); or
(iv) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab for that course.
For second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with tocilizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted tocilizumab supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.
(2) Treatment cycle.
Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count) or the prior therapy requirements, except if the patient has had a break in therapy of more than 12 months.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.
Where a patient is deemed to have failed to respond or to sustain a response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. The Department of Human Services will assess response according to these revised baseline measurements. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with the first course will be used by the Department of Human Services to assess response to the second course.
(4) Recommencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

Clinical criteria:

Patient must have been diagnosed with systemic juvenile idiopathic arthritis, AND

Patient must have received no prior PBS-subsidised treatment with tocilizumab for this condition; OR

Patient must not have received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months, AND

Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR

Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR

Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR

Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR

Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy; OR

Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 2 active joints; and

(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or

(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:

(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(ii) details of prior treatment including dose and duration of treatment;

(iii) pathology reports detailing CRP and platelet count where appropriate; and

(3) an acknowledgement signed by a parent or authorised guardian.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to 2 courses of treatment in a treatment cycle they will not be eligible to receive further PBS-subsidised tocilizumab therapy in that treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

Note To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be provided for all subsequent continuing treatment applications.

Note Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the

Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)

Clinical criteria:

Patient must have a documented history of systemic juvenile idiopathic arthritis, AND

Patient must have received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months, AND

Patient must not have failed to demonstrate an adequate response to PBS-subsidised therapy with tocilizumab for this condition more than once in the current treatment cycle, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to that course of treatment with tocilizumab.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

Note Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy under the Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy under the Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of systemic juvenile idiopathic arthritis, AND

Patient must have demonstrated an adequate response to their most recent course of PBS-subsidised treatment with tocilizumab, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the most recent prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

Note An assessment of the patient's response to a continuing course of therapy should be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

tocilizumab 200 mg/10 mL injection, 10 mL vial

1423X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	357.31	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

1464C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	704.03	Actemra [RO]

tocilizumab 80 mg/4 mL injection, 4 mL vial

1419Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	148.32	Actemra [RO]

Calcineurin inhibitors

▪ CYCLOSPORIN

Caution Careful monitoring of patients is mandatory.

Authority required

For use by organ or tissue transplant recipients

cyclosporin 50 mg/mL injection, 10 x 1 mL ampoules

6109M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	65.03	Sandimmun [NV]

▪ CYCLOSPORIN

Caution Careful monitoring of patients is mandatory.

Authority required

Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit. Management includes initiation, stabilisation and review of therapy as required

Authority required

Management (which includes initiation, stabilisation and review of therapy) by dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate

Authority required

Management (which includes initiation, stabilisation and review of therapy) by dermatologists of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life

Authority required

Management (which includes initiation, stabilisation and review of therapy) by nephrologists of patients with nephrotic syndrome in patients in whom steroids and cytostatic drugs have failed or are not tolerated or are considered inappropriate and in whom renal function is unimpaired

Authority required

Management (which includes initiation, stabilisation and review of therapy) by rheumatologists or clinical immunologists of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate

cyclosporin 10 mg capsule, 60

6232B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*85.33	Neoral 10 [NV]

cyclosporin 100 mg capsule, 30

6354K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*684.05	[a] Cyclosporin Sandoz [SZ]	[a] Neoral 100 [NV]

cyclosporin 100 mg/mL oral liquid, 50 mL

6125J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	4	5	..	*1310.09	Neoral [NV]

cyclosporin 25 mg capsule, 30

6352H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*166.65	[a] Cyclosporin Sandoz [SZ]	[a] Neoral 25 [NV]

cyclosporin 50 mg capsule, 30

6353J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*339.25	[a] Cyclosporin Sandoz [SZ]	[a] Neoral 50 [NV]

▪ TACROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority required

Management of rejection in patients following organ or tissue transplantation

Clinical criteria:

The treatment must be under the supervision and direction of a transplant unit, AND

The treatment must include initiation, stabilisation, and review of therapy as required.

tacrolimus 1 mg capsule, 100

6216E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*527.23	[a] Pharmacor Tacrolimus 1 [CR] [a] TACROLIMUS APOTEX [TX]	[a] Prograf [LL] [a] Tacrolimus Sandoz [SZ]

tacrolimus 1 mg capsule: modified release, 60

9682N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*319.09	Prograf XL [LL]

tacrolimus 5 mg capsule, 50

6217F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1297.01	[a] Pharmacor Tacrolimus 5 [CR] [a] TACROLIMUS APOTEX [TX]	[a] Prograf [LL] [a] Tacrolimus Sandoz [SZ]

tacrolimus 5 mg capsule: modified release, 30

9683P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*787.39	Prograf XL [LL]

tacrolimus 500 microgram capsule, 100

6328C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*267.07	[a] Pharmacor Tacrolimus 0.5 [CR] [a] TACROLIMUS APOTEX [TX]	[a] Prograf [LL] [a] Tacrolimus Sandoz [SZ]

tacrolimus 500 microgram capsule: modified release, 30

9681M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*85.97	Prograf XL [LL]

Other immunosuppressants

▪ LENALIDOMIDE

Note Special Pricing Arrangements apply.

Authority required

Myelodysplastic syndrome

Treatment Phase: Initial treatment

Clinical criteria:

The treatment must be limited to a maximum duration of 16 weeks, AND

Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), AND

Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, AND

Patient must be red blood cell transfusion dependent.

Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination: less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias.

Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations:

1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR
2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR
5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias.

Classification of a patient as red blood cell transfusion dependent requires that:

(i) the patient has been transfused within the last 8 weeks; and

(ii) the patient has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and would be expected to continue this requirement without lenalidomide treatment.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Myelodysplastic Syndrome Lenalidomide Authority Application - Supporting Information Form; and

(c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and

(d) a copy of the full blood examination report; and

(e) a copy of the pathology report detailing the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note: using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS -5q is acceptable); and

(f) details of transfusion requirements including: (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red cell units transfused in the 4 and 6 months preceding the date of this application; and

(g) a signed patient acknowledgement form.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), AND

Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, AND

Patient must have received PBS-subsidised initial therapy with lenalidomide for myelodysplastic syndrome, AND

Patient must have achieved and maintained transfusion independence; or least a 50% reduction in red blood cell unit transfusion requirements compared with the four month period prior to commencing initial PBS-subsidised therapy with lenalidomide, AND

Patient must not have progressive disease.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

The first authority application for continuing supply must be made in writing. Subsequent authority applications for continuing supply may be made by telephone.

The following evidence of response must be provided at each application:

(i) a haemoglobin level taken within the last 4 weeks; and

(ii) the date of the last transfusion; and

(iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application; and

(iv) a statement confirming that the patient has not progressed to acute myeloid leukaemia.

Note Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Subsequent authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

lenalidomide 10 mg capsule, 21

2796E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	3	..	5408.09	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

2798G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	3	..	5169.69	Revlimid [CJ]

HSD (Private)

▪ LENALIDOMIDE

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

Clinical criteria:

The condition must be confirmed by a histological diagnosis, AND

The treatment must be as monotherapy; OR

The treatment must be in combination with dexamethasone, AND

Patient must have progressive disease after at least one prior therapy, AND

Patient must have undergone or be ineligible for a primary stem cell transplant, AND

Patient must have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease, AND

Patient must not be receiving concomitant PBS-subsidised bortezomib.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Thalidomide treatment failure is defined as:

(1) confirmed disease progression during thalidomide treatment or within 6 months of discontinuing thalidomide treatment; or

(2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment.

Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living.

Toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity.

Failure to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease is defined as:

(1) less than a 25% reduction in serum or urine M protein; or

(2) in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum free light chain levels.

If the dosing requirement for thalidomide cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and

(3) duration of thalidomide and daily dose prescribed; and
(4) a signed patient acknowledgment.
To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:
(a) the level of serum monoclonal protein; or
(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
(c) the serum level of free kappa and lambda light chains; or
(d) bone marrow aspirate or trephine; or
(e) if present, the size and location of lytic bone lesions (not including compression fractures); or
(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
(g) if present, the level of hypercalcaemia, corrected for albumin concentration.
As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.
Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
Multiple myeloma
Treatment Phase: Continuing PBS-subsidised treatment
Clinical criteria:
Patient must have previously received an authority prescription for lenalidomide, AND
Patient must not have progressive disease, AND
The treatment must be as monotherapy; OR
The treatment must be in combination with dexamethasone.
Progressive disease is defined as at least 1 of the following:
(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).
Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

lenalidomide 10 mg capsule, 21

9643M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	5408.09	Revlimid [CJ]

lenalidomide 15 mg capsule, 21

9644N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	6299.46	Revlimid [CJ]

lenalidomide 25 mg capsule, 21

9645P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	6634.42	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9642L	1	..	..	5169.69	Revlimid [CJ]

▪ POMALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment

Clinical criteria:

The treatment must be in combination with dexamethasone, AND

Patient must have undergone or be ineligible for a primary stem cell transplant, AND

Patient must have experienced treatment failure with lenalidomide, AND

Patient must have experienced treatment failure with bortezomib, AND

Patient must not be receiving concomitant PBS-subsidised thalidomide, lenalidomide or bortezomib.

Bortezomib treatment failure is the absence of achieving at least a partial response or as progressive disease during treatment or within 6 months of discontinuing treatment with bortezomib. Lenalidomide treatment failure is progressive disease during treatment or within 6 months of discontinuing treatment with lenalidomide.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma pomalidomide Authority Application Supporting Information form; and

(3) reports demonstrating the patient has failed treatment with lenalidomide and bortezomib.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug, AND

Patient must not have progressive disease, AND

The treatment must be in combination with dexamethasone, AND

Patient must not be receiving concomitant PBS-subsidised thalidomide, lenalidomide or bortezomib.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

pomalidomide 3 mg capsule, 21

10417G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	10546.93	Pomalyst [CJ]

pomalidomide 4 mg capsule, 21

10386P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	10546.93	Pomalyst [CJ]

▪ RITUXIMAB

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the

baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis, AND

Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist, AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND

Patient must not have failed previous PBS-subsidised treatment with rituximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

Patient must not receive more than 2 infusions of rituximab under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'TNF' alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made at least 12 weeks after the first infusion so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services within 4 weeks of the date it was conducted. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient who fails to demonstrate a response to treatment with rituximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who fails to demonstrate a response to rituximab treatment and who qualifies to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist, AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND

Patient must not receive more than 2 infusions of rituximab under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'TNF' alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) completed authority prescription form(s); and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with rituximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised rituximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised rituximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response at least 12 weeks after the first infusion. This assessment must be submitted no later than 4 weeks from the date of the assessment.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient fails to demonstrate a response to a treatment with rituximab and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have demonstrated an adequate response to treatment with this drug, AND

Patient must have received this drug as the most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition, AND

Patient must not receive more than 2 infusions of rituximab under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) completed authority prescription form(s); and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

rituximab 500 mg/50 mL injection, 50 mL vial

9611W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	1945.85	Mabthera [RO]

▪ THALIDOMIDE

Caution Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program.

Authority required

Multiple myeloma

thalidomide 100 mg capsule, 28

9684Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	..	..	*1642.93	Thalomid [CJ]

thalidomide 50 mg capsule, 28

6469L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	4	..	..	*1642.93	Thalomid [CJ]

MUSCULO-SKELETAL SYSTEM

MUSCLE RELAXANTS

MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

Other centrally acting agents

BACLOFEN

Authority required
Severe chronic spasticity
Clinical criteria:
Patient must have failed to respond to treatment with oral antispastic agents; OR
Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND
Patient must have chronic spasticity of cerebral origin.

Authority required
Severe chronic spasticity
Clinical criteria:
Patient must have failed to respond to treatment with oral antispastic agents; OR
Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND
Patient must have chronic spasticity due to multiple sclerosis.

Authority required
Severe chronic spasticity
Clinical criteria:
Patient must have failed to respond to treatment with oral antispastic agents; OR
Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND
Patient must have chronic spasticity due to spinal cord injury.

Authority required
Severe chronic spasticity
Clinical criteria:
Patient must have failed to respond to treatment with oral antispastic agents; OR
Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND
Patient must have chronic spasticity due to spinal cord disease.

baclofen 10 mg/5 mL injection: intrathecal, 5 mL ampoule

6284R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
10	..	..	*1293.23	[a] Bacthecal [DZ]	[a] Lioresal Intrathecal [NV]

DRUGS FOR TREATMENT OF BONE DISEASES

DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

Bisphosphonates

IBANDRONATE

Authority required
Bone metastases
Clinical criteria:
The condition must be due to breast cancer.

ibandronate 6 mg/6 mL injection, 6 mL vial

9619G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	11	..	344.19	Bondronat [RO]

PAMIDRONATE DISODIUM

Authority required
Hypercalcaemia of malignancy
Clinical criteria:
Patient must have a malignancy refractory to anti-neoplastic therapy.

pamidronate disodium 15 mg/5 mL injection, 5 mL vial

6286W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	2	..	*66.17	Pamisol [HH]

pamidronate disodium 30 mg/10 mL injection, 10 mL vial

6287X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	2	..	*66.19	Pamisol [HH]

pamidronate disodium 60 mg/10 mL injection, 10 mL vial

6288Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	..	66.19	Pamisol [HH]

▪ PAMIDRONATE DISODIUM

Authority required
Hypercalcaemia of malignancy
Clinical criteria:
Patient must have a malignancy refractory to anti-neoplastic therapy.
Authority required
Multiple myeloma
Authority required
Bone metastases
Clinical criteria:
The condition must be due to breast cancer.

pamidronate disodium 90 mg/10 mL injection, 10 mL vial

6289B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	11	..	93.82	Pamisol [HH]

▪ ZOLEDRONIC ACID

Note Pharmaceutical benefits that have the form zoledronic acid 4 mg/100 mL injection and pharmaceutical benefits that have the form zoledronic acid 4 mg/5 mL injection are equivalent for the purposes of substitution.

Authority required
Multiple myeloma
Authority required
Bone metastases
Clinical criteria:
The condition must be due to breast cancer.
Authority required
Bone metastases
Clinical criteria:
The condition must be due to castration-resistant prostate cancer.
Authority required
Hypercalcaemia of malignancy
Clinical criteria:
Patient must have a malignancy refractory to anti-neoplastic therapy.

zoledronic acid 4 mg/100 mL injection, 100 mL bag

10542W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	11	..	346.98	[a] DBL Zoledronic Acid [HH]

zoledronic acid 4 mg/100 mL injection, 100 mL vial

10554L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	11	..	346.98	[a] Zometa [NV]

zoledronic acid 4 mg/5 mL injection, 5 mL vial

6371H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	11	..	346.98	[a] APO-Zoledronic Acid [TX] [a] Zometa [NV]	[a] DBL Zoledronic Acid [HH]

▪ NERVOUS SYSTEM

▪ ANTI-PARKINSON DRUGS

DOPAMINERGIC AGENTS

Dopa and dopa derivatives

▪ LEVODOPA + CARBIDOPA ANHYDROUS

Note Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.
Note A positive clinical response to Duodopa administered via a temporary nasoduodenal tube should be confirmed before a permanent percutaneous endoscopic gastrostomy (PEG) tube is inserted.

Authority required
Advanced Parkinson disease
Clinical criteria:
Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, AND

The treatment must be commenced in a hospital-based movement disorder clinic.

levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL

9744W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	8	5	..	*11582.93	Duodopa [VE]

Dopamine agonists

▪ APOMORPHINE

Authority required

Parkinson disease

Clinical criteria:

Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.

apomorphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules

10235Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	72	5	..	*3068.37	Apomine [HH]

apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules

9607P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	72	5	..	*6092.37	Movapo [TD]

apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules

9640J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	36	5	..	*7609.77	Movapo [TD]

▪ PSYCHOLEPTICS

ANTIPSYCHOTICS

Diazepines, oxazepines, thiazepines and oxepines

▪ CLOZAPINE

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Novartis Clozaril Patient Monitoring System (eCPMS) or Hospira Clopineconnect.

Authority required

Schizophrenia

Treatment Phase: Initial treatment

Clinical criteria:

Patient must be non-responsive to other neuroleptic agents; OR

Patient must be intolerant of other neuroleptic agents.

Treatment criteria:

Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient.

Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.

The name of the consulting psychiatrist should be included in the patient's medical records.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

clozapine 100 mg tablet, 100

6102E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*259.01	[a] Clopine 100 [HH]	[a] Clozaril 100 [NV]

clozapine 200 mg tablet, 100

6418T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	..	..	*511.09	Clopine 200 [HH]

clozapine 25 mg tablet, 100

6101D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*75.57	[a] Clopine 25 [HH]	[a] Clozaril 25 [NV]

clozapine 50 mg tablet, 100

6417R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	..	..	*141.39	Clopine 50 [HH]

clozapine 50 mg/mL oral liquid, 100 mL

9632Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	147.33	Clopine Suspension [HH]

RESPIRATORY SYSTEM

DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

Other systemic drugs for obstructive airway diseases

OMALIZUMAB

Note Special Pricing Arrangements apply.

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment

Clinical criteria:

Patient must be under the care of the same physician for at least 12 months, AND

Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, AND

Patient must have a duration of asthma of at least 1 year, AND

Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 3 or more occasions in the previous 12 months, AND

Patient must have past or current evidence of atopy, documented by skin prick testing or RAST, AND

Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL, AND

Patient must have signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, AND

Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, AND

Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 12 years or older.

Treatment criteria:

Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Optimised asthma therapy includes:

(i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or eformoterol 12 micrograms bd) for at least 12 months, unless contraindicated or not tolerated, AND

(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.

The initial IgE assessment must be no more than 12 months old at the time of application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 22 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form,
which includes the following:

(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(iii) the signed patient acknowledgement; and

(c) the IgE pathology report; and

(d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note It is recommended that an application for continuing treatment is submitted at the time of the 22 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA
Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.
Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised omalizumab therapy:
(a) Initial treatment:
Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.
(b) Continuing treatment:
Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.
(2) Baseline measurements to determine response:
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.
(4) Monitoring of patients:
Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment, AND

The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Note Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe allergic asthma, AND

Patient must have demonstrated or sustained an adequate response to treatment with this drug, AND

Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 18 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form which includes details of maintenance oral corticosteroid dose; and

(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

Note If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

Note For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA
Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised omalizumab therapy:
(a) Initial treatment:
Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.
(b) Continuing treatment:
Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.
(2) Baseline measurements to determine response:
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.
(4) Monitoring of patients:
Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

omalizumab 150 mg/mL injection, 1 mL syringe

10122R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	433.33	Xolair [NV]

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

10110D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	220.13	Xolair [NV]

▪ COUGH AND COLD PREPARATIONS

EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

Mucolytics

▪ DORNASE ALFA

Note This drug is not PBS-subsidised for use in combination with PBS-subsidised mannitol.

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

Authority required

Cystic fibrosis

Population criteria:

Patient must be 5 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Authority required

Cystic fibrosis

Clinical criteria:

Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR

Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR

Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR

Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.

Population criteria:

Patient must be less than 5 years of age.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented. Treatment with this drug should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have initiated treatment with dornase alfa at an age of less than 5 years, AND

Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

Population criteria:

Patient must be 5 years of age or older.

Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

dornase alfa 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules

6120D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	..	*2288.93	Pulmozyme [RO]

▪ MANNITOL

Note This drug is not PBS-subsidised for use in combination with PBS-subsidised dornase alfa.

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

Authority required

Cystic fibrosis

Clinical criteria:

Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result, AND

Patient must be intolerant or inadequately responsive to dornase alfa.

Population criteria:

Patient must be 6 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

MANNITOL Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers, 1

2008Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	4	5	..	*1782.93	bronchitol [XA]

OTHER RESPIRATORY SYSTEM PRODUCTS

OTHER RESPIRATORY SYSTEM PRODUCTS

Other respiratory system products

IVACAFTOR

Note Special Pricing Arrangements apply.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment – New patients

Clinical criteria:

Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, AND

Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR

Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, AND

Patient must not receive more than 24 weeks of treatment under this restriction, AND

The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

Patient must be 6 years of age or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and

(3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and

(4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and

(5) the result of a FEV1 measurement performed within a month prior to the date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and

(6) evidence that the patient has either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities; and

(7) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and

(8) a copy of a sweat chloride result; and

(9) height and weight measurements at the time of application; and

(10) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, AND

Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, AND

Patient must not receive more than 24 weeks of treatment under this restriction, AND

The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

Patient must be 6 years of age or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and

(3) the result of a FEV1 measurement performed within one month prior to the date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and

(4) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and

(5) a recent sweat chloride result; and

(6) height and weight measurements at the time of application; and

(7) a measurement of number of days of CF-related hospitalisation (including hospital in the home) in the previous 6 months.

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment - Grandfather patients

Clinical criteria:

Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, AND

Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR

Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, AND

Patient must have received treatment with ivacaftor for this condition prior to 1 December 2014, AND

Patient must have received treatment with ivacaftor within the last 6 months at the time of application, AND

Patient must not receive more than 24 weeks of treatment under this restriction, AND

The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

Patient must be 6 years of age or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Cystic Fibrosis Ivacaftor Application Supporting Information Form; and

(3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and

(4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene performed prior to commencing treatment with ivacaftor; and

(5) the result of a FEV1 measurement performed prior to commencing treatment with ivacaftor for this condition; and

(6) the result of a FEV1 measurement performed within a month prior to date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and

(7) evidence that the patient had either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities prior to commencing treatment with ivacaftor for this condition; and

(8) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and

(9) a copy of sweat chloride result performed prior to commencing treatment with ivacaftor for this condition; and

(10) a recent sweat chloride result prior to commencing PBS-subsidised ivacaftor; and

(11) height and weight measurements at the time of application; and

(12) height and weight measurements performed immediately prior to commencement of ivacaftor; and

(13) a baseline measurement of number of days of CF-related hospitalisation (including hospital-in-the home) in the 12 months prior to commencement of ivacaftor; and

(14) a measurement of the number of days of CF-related hospitalisation (including hospital-in the home) in the 6 months prior to the date of application; and

(15) dates of prior ivacaftor therapy.

ivacaftor 150 mg tablet, 56

10175M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	22546.93	Kalydeco [VR]

▪ VARIOUS

▪ ALL OTHER THERAPEUTIC PRODUCTS

ALL OTHER THERAPEUTIC PRODUCTS

Iron chelating agents

▪ DEFERASIROX

Note Special Pricing Arrangements apply.

Authority required

Chronic iron overload in patients with disorders of erythropoiesis

deferasirox 125 mg tablet: dispersible, 28

6499C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6	5	..	*1378.35	Exjade [NV]

deferasirox 250 mg tablet: dispersible, 28

6500D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	5	..	*2709.69	Exjade [NV]

deferasirox 500 mg tablet: dispersible, 28

9600G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	5	..	*5372.49	Exjade [NV]

▪ DEFERIPRONE

Authority required

Iron overload in patients with thalassaemia major who are unable to take desferrioxamine therapy

Authority required

Iron overload in patients with thalassaemia major in whom desferrioxamine therapy has proven ineffective

deferiprone 100 mg/mL oral liquid, 250 mL

9638G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	5	5	..	*1117.03	Ferriprox [TX]

deferiprone 500 mg tablet, 100

6416Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	5	..	*2615.13	Ferriprox [TX]

▪ DESFERRIOXAMINE

Authority required

Disorders of erythropoiesis associated with treatment-related chronic iron overload

desferrioxamine mesylate 2 g injection, 1 vial

6270B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	60	5	..	*1771.53	Hospira Pty Limited [HH]

desferrioxamine mesylate 500 mg injection, 10 vials

6113R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	40	5	..	*6793.33	Hospira Pty Limited [HH]

Drugs for treatment of hyperkalemia and hyperphosphatemia

▪ LANTHANUM

Authority required

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

Clinical criteria:

The condition must not be adequately controlled by calcium, AND

Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR

The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND

The treatment must not be used in combination with any other non-calcium phosphate binding agents.

Treatment criteria:

Patient must be undergoing dialysis for chronic kidney disease.

LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90

9637F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*886.27	Fosrenol [ZI]

LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90

9635D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*524.19	Fosrenol [ZI]

LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90

9636E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*788.01	Fosrenol [ZI]

▪ SEVELAMER

Authority required

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

Clinical criteria:

The condition must not be adequately controlled by calcium, AND
Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND
The treatment must not be used in combination with any other non-calcium phosphate binding agents.
Treatment criteria:
Patient must be undergoing dialysis for chronic kidney disease.

sevelamer hydrochloride 800 mg tablet, 180

9620H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*619.49	Renagel [GZ]

▪ SUCROFERRIC OXYHYDROXIDE

Authority required
Hyperphosphataemia
Treatment Phase: Initiation and stabilisation
Clinical criteria:
The condition must not be adequately controlled by calcium, AND
Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND
The treatment must not be used in combination with any other non-calcium phosphate binding agents.
Treatment criteria:
Patient must be undergoing dialysis for chronic kidney disease.

iron (as sucroferric oxyhydroxide) 500 mg tablet: chewable, 90

10230K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*790.53	Velphoro [FN]

Highly Specialised Drugs Program (Public Hospital)

HSD (Public)

BLOOD AND BLOOD FORMING ORGANS

ANTIHEMORRHAGICS

VITAMIN K AND OTHER HEMOSTATICS

Other systemic hemostatics

ELTROMBOPAG

Note Eltrombopag is not PBS-subsidised as an alternative to splenectomy.
Any queries concerning the arrangements to prescribe eltrombopag may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authority to prescribe eltrombopag should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001
Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

Note Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.
No applications for increased repeats will be authorised.

Note No applications for increased repeats will be authorised.

Authority required

Initial (new patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:

(1) Splenectomised and:

(a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and

(b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;

OR

(2) Not splenectomised and:

(a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and

(b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and

(c) in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:

(a) a platelet count of less than or equal to 20,000 million per L;

OR

(b) a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],

(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and

(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion

Authority required

Initial (grandfather patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with eltrombopag prior to 1 November 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time eltrombopag was commenced.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and

(4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion

Authority required

Continuing therapy or re-initiation after a break in therapy

First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with eltrombopag during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised eltrombopag,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include:

(1) a completed authority prescription form, and

(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and

(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The most recent platelet count must be no more than one month old at the time of application.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone

Authority required

Second and subsequent applications for continuing therapy

Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with eltrombopag and who continues to display a response to treatment with eltrombopag.

For the purposes of this restriction, a continuing response to treatment with eltrombopag is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with eltrombopag,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

Platelet counts must be no more than 1 month old at the time of application.

Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

eltrombopag 25 mg tablet, 28

5825N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	1512.00	Revolade [NV]

eltrombopag 50 mg tablet, 28

5826P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	3024.00	Revolade [NV]

▪ ROMIPLOSTIM

Note Romiplostim is not PBS-subsidised as an alternative to splenectomy.
Any queries concerning the arrangements to prescribe romiplostim may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authority to prescribe romiplostim should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001
Further prescribing information is on the Medicare Australia website at www.medicareaustralia.gov.au.

Note Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS-subsidised treatment with either of these drugs.

Note Special Pricing Arrangements apply.

Authority required

Initial (new patients)

Initial treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:

(1) Splenectomised and:

(a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and

(b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;

OR

(2) Not splenectomised and:

(a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and

(b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and

(c) in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:

(a) a platelet count of less than or equal to 20,000 million per L;

OR

(b) a platelet count of 20-30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)],

(4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and

(5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

Authority required

Initial (grandfather patients)

Initial PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with romiplostim prior to 1 April 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time romiplostim was commenced.

The authority application must be made in writing and must include:

(1) a completed authority prescription form,

(2) a signed patient acknowledgement,

(3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and

(4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

For patients whose dose of romiplostim had been stable for at least 4 weeks at the time of the initial application for PBS-subsidy, the medical practitioner should request sufficient number of vials based on the weight of the patient and dose (microgram/kg/week) to provide up to 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where the patient is in the titration phase of treatment with romiplostim, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application.

Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The dose (microgram/kg/week) must be provided at the time of application.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

Authority required

Continuing therapy or re-initiation after a break in therapy

First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with romiplostim during the initial period of PBS-subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised romiplostim,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include:

(1) a completed authority prescription form, and

(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)], and

(3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy).

The most recent platelet count must be no more than one month old at the time of application.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

Authority required

Second and subsequent applications for continuing therapy

Continuing treatment, as the sole PBS-subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with romiplostim and who continues to display a response to treatment with romiplostim.

For the purposes of this restriction, a continuing response to treatment with romiplostim is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with romiplostim,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

Platelet counts must be no more than 1 month old at the time of application.

Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses of higher than 10 micrograms/kg/week

romiplostim 250 microgram injection, 1 vial

9696H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	928.63	Nplate [AN]

romiplostim 500 microgram injection, 1 vial

9698K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	1857.25	Nplate [AN]

ANTIANEMIC PREPARATIONS

OTHER ANTIANEMIC PREPARATIONS

Other antianemic preparations

DARBEPOETIN ALFA

Authority required (STREAMLINED)

3334

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

darbepoetin alfa 10 microgram/0.4 mL injection, 4 x 0.4 mL syringes

5637Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*338.28	Aranesp [AN]

darbepoetin alfa 100 microgram/0.5 mL injection, 0.5 mL syringe

5649H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	8	5	..	*2489.44	Aranesp SureClick [AN]

darbepoetin alfa 100 microgram/0.5 mL injection, 4 x 0.5 mL syringes

5651K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*2489.48	Aranesp [AN]

darbepoetin alfa 150 microgram/0.3 mL injection, 0.3 mL syringe

5650J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	8	5	..	*3709.28	Aranesp SureClick [AN]

darbepoetin alfa 150 microgram/0.3 mL injection, 4 x 0.3 mL syringes

5643B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*3709.28	Aranesp [AN]

darbepoetin alfa 20 microgram/0.5 mL injection, 0.5 mL syringe

5645D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	8	5	..	*637.12	Aranesp SureClick [AN]

darbepoetin alfa 20 microgram/0.5 mL injection, 4 x 0.5 mL syringes

5638R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*637.08	Aranesp [AN]

darbepoetin alfa 30 microgram/0.3 mL injection, 4 x 0.3 mL syringes

5639T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*871.58	Aranesp [AN]

darbepoetin alfa 40 microgram/0.4 mL injection, 0.4 mL syringe

5646E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	8	5	..	*1057.92	Aranesp SureClick [AN]

darbepoetin alfa 40 microgram/0.4 mL injection, 4 x 0.4 mL syringes

5640W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1057.92	Aranesp [AN]

darbepoetin alfa 50 microgram/0.5 mL injection, 4 x 0.5 mL syringes

5641X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1307.94	Aranesp [AN]

darbepoetin alfa 60 microgram/0.3 mL injection, 0.3 mL syringe

5647F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	8	5	..	*1535.84	Aranesp SureClick [AN]

darbepoetin alfa 60 microgram/0.3 mL injection, 4 x 0.3 mL syringes

5642Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1535.82	Aranesp [AN]

darbepoetin alfa 80 microgram/0.4 mL injection, 0.4 mL syringe

5648G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	8	5	..	*2021.60	Aranesp SureClick [AN]

darbepoetin alfa 80 microgram/0.4 mL injection, 4 x 0.4 mL syringes

5644C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*2021.60	Aranesp [AN]

▪ EPOETIN ALFA

Authority required (STREAMLINED)

3334

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

epoetin alfa 10 000 units/mL injection, 6 x 1 mL syringes

5722E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1871.78	Eprex 10000 [JC]

epoetin alfa 1000 units/0.5 mL injection, 6 x 0.5 mL syringes

5714R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*265.34	Eprex 1000 [JC]

epoetin alfa 20 000 units/0.5 mL injection, 6 x 0.5 mL syringes

5713Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*3682.20	Eprex 20,000 [JC]

epoetin alfa 2000 units/0.5 mL injection, 6 x 0.5 mL syringes

5719B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*490.96	Eprex 2000 [JC]

epoetin alfa 3000 units/0.3 mL injection, 6 x 0.3 mL syringes

5720C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*633.56	Eprex 3000 [JC]

epoetin alfa 40 000 units/mL injection, 1 mL syringe

5718Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1191.30	Eprex 40,000 [JC]

epoetin alfa 4000 units/0.4 mL injection, 6 x 0.4 mL syringes

5721D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*806.84	Eprex 4000 [JC]

epoetin alfa 5000 units/0.5 mL injection, 6 x 0.5 mL syringes

5715T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1004.48	Eprex 5000 [JC]

epoetin alfa 6000 units/0.6 mL injection, 6 x 0.6 mL syringes

5716W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1192.38	Eprex 6000 [JC]

epoetin alfa 8000 units/0.8 mL injection, 6 x 0.8 mL syringes

5717X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1546.52	Eprex 8000 [JC]

▪ EPOETIN BETA

Authority required (STREAMLINED)

3334

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

epoetin beta 10 000 units/0.6 mL injection, 6 x 0.6 mL syringes

5729M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1871.78	NeoRecormon [RO]

epoetin beta 2000 units/0.3 mL injection, 6 x 0.3 mL syringes

5724G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*490.96	NeoRecormon [RO]

epoetin beta 3000 units/0.3 mL injection, 6 x 0.3 mL syringes

5725H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*633.56	NeoRecormon [RO]

epoetin beta 4000 units/0.3 mL injection, 6 x 0.3 mL syringes

5726J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*806.84	NeoRecormon [RO]

epoetin beta 5000 units/0.3 mL injection, 6 x 0.3 mL syringes

5727K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1004.50	NeoRecormon [RO]

epoetin beta 6000 units/0.3 mL injection, 6 x 0.3 mL syringes

5728L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1192.38	NeoRecormon [RO]

▪ EPOETIN LAMBDA

Note Epoetin lambda should only be administered by the intravenous route.

Authority required (STREAMLINED)

3334

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

epoetin lambda 10 000 units/mL injection, 6 x 1 mL syringes

9596C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1773.28	Novicrit [SZ]

epoetin lambda 1000 units/0.5 mL injection, 6 x 0.5 mL syringes

9668W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*251.38	Novicrit [SZ]

epoetin lambda 2000 units/mL injection, 6 x 1 mL syringes

9669X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*465.12	Novicrit [SZ]

epoetin lambda 3000 units/0.3 mL injection, 6 x 0.3 mL syringes

9670Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*600.22	Novicrit [SZ]

epoetin lambda 4000 units/0.4 mL injection, 6 x 0.4 mL syringes

9587N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*764.38	Novicrit [SZ]

epoetin lambda 5000 units/0.5 mL injection, 6 x 0.5 mL syringes

9589Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*951.62	Novicrit [SZ]

epoetin lambda 6000 units/0.6 mL injection, 6 x 0.6 mL syringes

9591T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1129.62	Novicrit [SZ]

epoetin lambda 8000 units/0.8 mL injection, 6 x 0.8 mL syringes

9594Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1465.12	Novicrit [SZ]

▪ METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA

Authority required (STREAMLINED)

3334

Treatment of anaemia requiring transfusion, defined as a haemoglobin level of less than 100 g per L, where intrinsic renal disease, as assessed by a nephrologist, is the primary cause of the anaemia

methoxy polyethylene glycol-epoetin beta 100 microgram/0.3 mL injection, 1 x 0.3 mL syringe

5797D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1100.88	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 120 microgram/0.3 mL injection, 1 x 0.3 mL syringe

5798E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1274.56	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 200 microgram/0.3 mL injection, 1 x 0.3 mL syringe

5799F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1828.08	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 30 microgram/0.3 mL injection, 1 x 0.3 mL syringe

5794Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*350.72	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 360 microgram/0.6 mL injection, 1 x 0.6 mL syringe

5800G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*3160.20	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 50 microgram/0.3 mL injection, 1 x 0.3 mL syringe

5795B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*584.54	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 75 microgram/0.3 mL injection, 1 x 0.3 mL syringe

5796C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*851.22	Mircera [RO]

CARDIOVASCULAR SYSTEM

ANTIHYPERTENSIVES

OTHER ANTIHYPERTENSIVES

Antihypertensives for pulmonary arterial hypertension

AMBRISENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition, AND

The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR

Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Patients who have previously received PBS-subsidised treatment with this drug for this condition under the Continuing treatment (all patients) prior to 1 May 2016 are eligible to continue PBS subsidised treatment with this drug under this criteria.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

ambrisentan 10 mg tablet, 30

5608E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	2732.65	Volibris [GK]

ambrisentan 5 mg tablet, 30

5607D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	2732.65	Volibris [GK]

HSD (Public)

▪ BOSENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.
The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.
The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.
The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition, AND

The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR

Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Patients who have previously received PBS-subsidised treatment with this drug for this condition under the Continuing treatment (all patients) prior to 1 May 2016 are eligible to continue PBS subsidised treatment with this drug under this criteria.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

bosentan 125 mg tablet, 60

5619R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	2732.65	Tracleer [AT]

▪ BOSENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.
The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.
The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
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HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information. No repeats will be authorised for this prescription.

The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap

therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Where the 62.5 mg tablet strength is required for the second authority prescription, please contact the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice.
The approved second authority prescription will be returned to the prescriber by the Department of Human Services two weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the six months initial treatment course. The Department of Human Services will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

HSD (Public)

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition, AND

The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR

Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Patients who have previously received PBS-subsidised treatment with this drug for this condition under the Continuing treatment (all patients) prior to 1 May 2016 are eligible to continue PBS subsidised treatment with this drug under this criteria.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Cessation of treatment (all patients)

Clinical criteria:

Patient must have received approval for initial PBS-subsidised treatment with this agent, AND

Patient must have not responded to prior PBS-subsidised therapy with this agent, AND

The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

bosentan 62.5 mg tablet, 60

5618Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	2732.65	Tracleer [AT]

▪ EPOPROSTENOL

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 micrograms (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and

(4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It

also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 1.5 mg (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 1.5 mg injection vial are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form epoprostenol sodium powder for I.V. infusion 500 micrograms (base) infusion administration set and pharmaceutical benefits that have the form epoprostenol 500 microgram injection vial are equivalent for the purposes of substitution.

HSD (Public)

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients) or Initial 2 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition, AND

The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR

Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Patients who have previously received PBS-subsidised treatment with this drug for this condition under the Continuing treatment (all patients) prior to 1 May 2016 are eligible to continue PBS subsidised treatment with this drug under this criteria.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

EPOPROSTENOL SODIUM Powder for I.V. infusion 1.5 mg (base) infusion administration set, 1

5035B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	66.55	[a] Flolan Kit [GK]

EPOPROSTENOL SODIUM Powder for I.V. infusion 500 micrograms (base) infusion administration set, 1

5030R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	33.28	[a] Flolan Kit [GK]

epoprostenol 1.5 mg injection, 1 vial

10117L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	66.55	[a] Veletri [AT]

epoprostenol 500 microgram injection, 1 vial

10130E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	33.28	[a] Veletri [AT]

▪ ILOPROST

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with this agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III drug-induced PAH, AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note Special Pricing Arrangements apply.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III drug-induced PAH and a mean right atrial pressure greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III drug-induced PAH with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

Patient must have WHO Functional Class IV drug-induced PAH, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
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HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note Special Pricing Arrangements apply.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or drug-induced PAH and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have received prior treatment with a PBS-subsidised PAH agent other than this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must have failed to respond to a prior PBS-subsidised PAH agent, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and

(4) for WHO Functional Class III patients, where this is the first application for this agent, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Note Special Pricing Arrangements apply.

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition, AND

The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR

Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Patients who have previously received PBS-subsidised treatment with this drug for this condition under the Continuing treatment (all patients) prior to 1 May 2016 are eligible to continue PBS subsidised treatment with this drug under this criteria.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

iloprost 20 microgram/2 mL inhalation: solution, 30 x 2 mL ampoules

5751Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	408.88	Ventavis [BN]

▪ MACITENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class IV idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; OR

Patient must have WHO Functional Class III or IV pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease or PAH associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

A maximum of 5 repeats will be authorised.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition, AND

The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR

Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Patients who have previously received PBS-subsidised treatment with this drug for this condition under the Continuing treatment (all patients) prior to 1 May 2016 are eligible to continue PBS subsidised treatment with this drug under this criteria.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

macitentan 10mg tablet, 30

10136L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	2876.47	Opsumit [AT]

▪ SILDENAFIL

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated,

details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition, AND

The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR

Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Patients who have previously received PBS-subsidised treatment with this drug for this condition under the Continuing treatment (all patients) prior to 1 May 2016 are eligible to continue PBS subsidised treatment with this drug under this criteria.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

sildenafil 20 mg tablet, 90

9547L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	514.77	[a] APO-Sildenafil PHT [TX] [a] Sildenafil AN PHT 20 [EA] [a] Sildenafil Sandoz PHT 20 [SZ]	[a] Revatio [PF] [a] SILDENAFIL-DRx [RZ]

▪ TADALAFIL

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease, AND

Patient must have a mean right atrial pressure of 8 mmHg or less as measured by right heart catheterisation (RHC); OR

Patient must have right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds, AND

Patient must have failed to respond to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details of the nature of the adverse event or contraindication according to the Therapeutic Goods Administration (TGA) approved Product Information must also be provided with the application.

Response to prior vasodilator treatment is defined as follows:

For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

HSD (Public)

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (new patients)

Clinical criteria:

Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, AND

Patient must have been assessed by a physician at a designated hospital, AND

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, and a mean right atrial pressure of greater than 8 mmHg, as measured by right heart catheterisation (RHC); OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH), or anorexigen-induced PAH or hereditable PAH, with right ventricular function assessed by echocardiography (ECHO) where a RHC cannot be performed on clinical grounds; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC; OR

Patient must have WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease with right ventricular function assessed by ECHO where a RHC cannot be performed on clinical grounds, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT); and

(3) a signed patient acknowledgement.

Idiopathic pulmonary arterial hypertension, anorexigen-induced pulmonary arterial hypertension, hereditable pulmonary arterial hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Test requirements to establish baseline for initiation of treatment are as follows:

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
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Complex Drugs
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HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 (change or re-commencement of therapy for all patients)

Clinical criteria:

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and must wish to re-commence PBS-subsidised therapy with this agent after a break in therapy and must have demonstrated a response to their most recent course of PBS-subsidised treatment with this agent; OR

Patient must have WHO Functional Class III idiopathic pulmonary arterial hypertension (iPAH) or anorexigen-induced PAH or hereditable PAH or PAH secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with a PAH agent other than this agent, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form; and

(3) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be provided with the authority application.

The test results provided must not be more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

The assessment of the patient's response to the initial 6 month course of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 7 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to

that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. New baselines may be submitted where the patient has failed to respond to their current treatment.

Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

For eligible patients, applications to swap between the 7 PAH agents must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

Note Applications for patients who wish to swap to an alternate PAH agent should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

HSD (Public)

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 or Initial 2 (new patients) or Initial 3 (change or re-commencement of therapy for all patients) or First Continuing treatment - Balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this agent under the Initial 1 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 2 (new patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the Initial 3 (change or re-commencement of therapy for all patients) restriction to complete a maximum of six months of treatment; OR

Patient must have received insufficient therapy with this agent under the First Continuing treatment restriction to complete a maximum of six months of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition, AND

The treatment must provide no more than the balance of up to six months treatment available under one of the above restrictions.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: First Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised initial course of treatment with this agent for this condition, AND

Patient must have been assessed by a physician from a designated hospital to have achieved a response to the PBS-subsidised initial course of treatment, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form which includes results from the three tests below, where available:

(i) RHC composite assessment; and

(ii) ECHO composite assessment; and

(iii) 6 Minute Walk Test (6MWT).

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with the written First Continuing treatment application, except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

Response to a PAH agent is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least one of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for First Continuing treatment with a PAH agent should be made prior to the completion of the Initial 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Subsequent Continuing treatment

Clinical criteria:

Patient must have received a PBS-subsidised treatment under First Continuing treatment with this agent for this condition; OR

Patient must have previously received PBS-subsidised treatment under this criteria with this agent for this condition, AND

The treatment must be the sole PBS-subsidised PAH agent for this condition.

Patients who have previously received PBS-subsidised treatment with this drug for this condition under the Continuing treatment (all patients) prior to 1 May 2016 are eligible to continue PBS subsidised treatment with this drug under this criteria.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats will be authorised.

An application for Subsequent Continuing treatment with a PAH agents should be made prior to the completion of the First Continuing treatment course to ensure continuity of treatment.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The term 'PAH agents' refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan, tadalafil, and macitentan.

Note Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authorisation under this criterion should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Refer to the Department of Human Services website at www.humanservices.gov.au for a list of designated hospitals.

tadalafil 20 mg tablet, 56

1308W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	838.53	Adcirca [LY]

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

HYPOTHALAMIC HORMONES

Somatostatin and analogues

LANREOTIDE

Authority required (STREAMLINED)

4567

Acromegaly

Clinical criteria:

The condition must be active, AND

Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, AND

The treatment must be after failure of other therapy including dopamine agonists; OR

The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR

The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, AND

The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (6 weeks after the last dose), AND

The treatment must cease if IGF1 is not lower after 3 months of treatment.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

lanreotide 30 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL ampoule], 1 pack

5776B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	11	..	*1425.00	Somatuline LA [IS]

LANREOTIDE

Authority required (STREAMLINED)

4570

Acromegaly

Clinical criteria:

The condition must be active, AND

Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, AND

The treatment must be after failure of other therapy including dopamine agonists; OR

The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR

The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, AND

The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), AND

The treatment must cease if IGF1 is not lower after 3 months of treatment.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Authority required (STREAMLINED)

4575

Functional carcinoid tumour

Clinical criteria:

The condition must be causing intractable symptoms, AND

Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, AND

Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, AND

The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

lanreotide 120 mg injection, 1 syringe

5779E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	..	*4256.00	Somatuline Autogel [IS]

lanreotide 60 mg injection, 1 syringe

5777C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*2555.50	Somatuline Autogel [IS]

lanreotide 90 mg injection, 1 syringe

5778D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*3401.00	Somatuline Autogel [IS]

▪ OCTREOTIDE

Authority required (STREAMLINED)

3407

Active acromegaly in a patient with persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre AND

(a) after failure of other therapy including dopamine agonists; or

(b) as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or

(c) if the patient is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated.

In a patient treated with radiotherapy, treatment must cease if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks. Octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Treatment must cease if IGF1 is not lower after 3 months treatment at a dose of 100 micrograms 3 times daily

Authority required (STREAMLINED)

3408

Functional carcinoid tumour or vasoactive intestinal peptide secreting tumour (VIPoma) causing intractable symptoms. The patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, and surgery or antineoplastic therapy must have failed or be inappropriate.

Treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose

octreotide 100 microgram/mL injection, 5 x 1 mL ampoules

9509L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	18	11	..	*1236.42	[a] Hospira Pty Limited [HH]	[a] Octreotide MaxRx [GQ]
					[a] Octreotide (SUN) [RA]	[a] Sandostatin 0.1 [NV]

octreotide 50 microgram/mL injection, 5 x 1 mL ampoules

9508K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	18	11	..	*619.02	[a] Hospira Pty Limited [HH]	[a] Octreotide MaxRx [GQ]
					[a] Octreotide (SUN) [RA]	[a] Sandostatin 0.05 [NV]

octreotide 500 microgram/mL injection, 5 x 1 mL ampoules

9510M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	18	11	..	*6194.52	[a] Hospira Pty Limited [HH]	[a] Octreotide MaxRx [GQ]
					[a] Octreotide (SUN) [RA]	[a] Sandostatin 0.5 [NV]

▪ OCTREOTIDE

Authority required (STREAMLINED)

5900

Acromegaly

Clinical criteria:

The condition must be controlled with octreotide immediate release injections, AND

The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), AND

The treatment must cease if IGF1 is not lower after 3 months of treatment.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

Authority required (STREAMLINED)

5901

Functional carcinoid tumour

Clinical criteria:

Patient must have achieved symptom control on octreotide immediate release injections, AND

The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

Authority required (STREAMLINED)

5906
Vasoactive intestinal peptide secreting tumour (VIPoma)
Clinical criteria:
Patient must have achieved symptom control on octreotide immediate release injections, AND
The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.
Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

octreotide 10 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10543X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*2613.72	Sandostatin LAR [NV]

octreotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10533J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*3479.62	Sandostatin LAR [NV]

octreotide 30 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10550G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*4354.92	Sandostatin LAR [NV]

HSD (Public)

ANTIINFECTIVES FOR SYSTEMIC USE

ANTIBACTERIALS FOR SYSTEMIC USE

MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

Macrolides

AZITHROMYCIN

Authority required (STREAMLINED)
3317
Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre

azithromycin 600 mg tablet, 8

5616N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*110.76	Zithromax [PF]

CLARITHROMYCIN

Authority required (STREAMLINED)
5874
Mycobacterium avium complex infection

clarithromycin 500 mg tablet, 100

5624B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	2	..	35.23	APO-Clarithromycin [TX]

ANTIMYCOBACTERIALS

DRUGS FOR TREATMENT OF TUBERCULOSIS

Antibiotics

RIFABUTIN

Authority required (STREAMLINED)
3415
Treatment of Mycobacterium avium complex infections in HIV-positive patients
Authority required (STREAMLINED)
3317
Prophylaxis against Mycobacterium avium complex infections in HIV-positive patients with CD4 cell counts of less than 75 per cubic millimetre

rifabutin 150 mg capsule, 30

9541E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	4	5	..	*615.00	Mycobutin [PF]

ANTIVIRALS FOR SYSTEMIC USE

DIRECT ACTING ANTIVIRALS

Nucleosides and nucleotides excl. reverse transcriptase inhibitors

GANCICLOVIR

Authority required (STREAMLINED)

4972

Cytomegalovirus disease

Treatment Phase: Prophylaxis

Clinical criteria:

Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.

Authority required (STREAMLINED)

4999

Cytomegalovirus disease

Treatment Phase: Prophylaxis

Clinical criteria:

Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

ganciclovir 500 mg injection, 5 vials

5749N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	1	..	*532.00	Cymevene [RO]

RIBAVIRIN

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 24 weeks.

Population criteria:

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

ribavirin 400 mg tablet, 28

10646H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	140.00	Ibavyr [IX]

ribavirin 600 mg tablet, 28

10638X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	210.00	Ibavyr [IX]

RIBAVIRIN

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 12 weeks.

Population criteria:

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

ribavirin 400 mg tablet, 28

10678B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	..	140.00	Ibavyr [IX]

ribavirin 600 mg tablet, 28

10663F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	2	..	210.00	Ibavyr [IX]

▪ VALACICLOVIR

Authority required (STREAMLINED)

5975

Cytomegalovirus infection and disease

Treatment Phase: Prophylaxis

Clinical criteria:

Patient must have undergone a renal transplant, AND

Patient must be at risk of cytomegalovirus disease.

valaciclovir 500 mg tablet, 100

9568N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*420.00	[a] APO-Valaciclovir [TX] [a] Valtrex [RW]	[a] Valaciclovir RBX [RA] [a] Zelitrex [RF]

▪ VALGANCICLOVIR

Authority required (STREAMLINED)

4989

Cytomegalovirus infection and disease

Treatment Phase: Prophylaxis

Clinical criteria:

Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

valganciclovir 450 mg tablet, 60

9569P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*4267.02	Valcyte [RO]

valganciclovir 50 mg/mL oral liquid: powder for, 100 mL

9655E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	11	5	..	*4346.10	Valcyte [RO]

Protease inhibitors

▪ BOCEPREVIR

Note No increase in the maximum quantity or number of units may be authorised.

Note Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

Authority required (STREAMLINED)

4182

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease, AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C, AND

The treatment must be in combination with peginterferon alfa and ribavirin, AND

The treatment must be limited to a maximum duration of 32 weeks in patients without hepatic cirrhosis who were partial responders or relapsers to the prior course of interferon based therapy for hepatitis C; OR

The treatment must be limited to a maximum duration of 44 weeks in patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy for hepatitis C; OR

The treatment must be limited to a maximum duration of 44 weeks for all patients with hepatic cirrhosis, AND

The treatment must cease after the first 8 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 12, AND

The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24.

Population criteria:

Patient must be 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.

For patients without hepatic cirrhosis who were partial responders or relapsers to the prior course of interferon based therapy, a maximum of 7 repeats may be prescribed.

For patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy, a maximum of 10 repeats may be prescribed.

For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed.

Authority required (STREAMLINED)

4202

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease, AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND

The treatment must be in combination with peginterferon alfa and ribavirin, AND

The treatment must be limited to a maximum duration of 24 weeks in patients without hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 44 weeks in patients with hepatic cirrhosis, AND

The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24.

Population criteria:

Patient must be 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.

For patients without hepatic cirrhosis, a maximum of 5 repeats may be prescribed.

For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed.

boceprevir 200 mg capsule, 336

2433C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	10	..	3920.00	Victrelis [MK]

▪ SIMEPREVIR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

Authority required

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease, AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND

The treatment must be in combination with peginterferon alfa and ribavirin, AND

The treatment must be limited to a maximum duration of 12 weeks, AND

The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is 25 IU/mL or greater.

Population criteria:

Patient must be aged 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised simeprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.

Authority required

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease, AND

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C, AND

The treatment must be in combination with peginterferon alfa and ribavirin, AND

The treatment must be limited to a maximum duration of 12 weeks, AND

The treatment must cease if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is 25 IU/mL or greater.

Population criteria:

Patient must be 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised simeprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.

simeprevir sodium 150 mg capsule, 7

10200W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	..	..	*14865.72	Olysio [JC]

Other antivirals

▪ DACLATASVIR

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 24 weeks.

daclatasvir 30 mg tablet, 28

10629K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	..	7666.67	Daklinza [BQ]

daclatasvir 60 mg tablet, 28

10641C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	..	7666.67	Daklinza [BQ]

▪ DACLATASVIR

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 12 weeks.

daclatasvir 30 mg tablet, 28

10651N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	2	..	7666.67	Daklinza [BQ]

daclatasvir 60 mg tablet, 28

10660C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	2	..	7666.67	Daklinza [BQ]

▪ LEDIPASVIR + SOFOSBUVIR

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection
Clinical criteria:
Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
The treatment must be limited to a maximum duration of 12 weeks.

ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

10661D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	..	22066.67	Harvoni [GI]

▪ LEDIPASVIR + SOFOSBUVIR

HSD (Public)

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection
Clinical criteria:
Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
The treatment must be limited to a maximum duration of 8 weeks.

ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

10667K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	1	..	22066.67	Harvoni [GI]

▪ LEDIPASVIR + SOFOSBUVIR

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection
Clinical criteria:
Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
The treatment must be limited to a maximum duration of 24 weeks.

ledipasvir 90 mg + sofosbuvir 400 mg tablet, 28

10669M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	22066.67	Harvoni [GI]

▪ PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required
Chronic hepatitis C infection
Clinical criteria:
Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND
Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND
The treatment must be limited to a maximum duration of 12 weeks.

paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56], 4 x 28

10751W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	..	13853.13	Viekira Pak [VE]

▪ PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR & RIBAVIRIN

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 24 weeks.

Population criteria:

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 200 mg tablet [168], 1 pack

10752X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	13853.13	Viekira Pak-RBV [VE]

paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 600 mg tablet [56], 1 pack

10768R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	13853.13	Viekira Pak-RBV [VE]

▪ PARITAPREVIR + RITONAVIR + OMBITASVIR & DASABUVIR & RIBAVIRIN

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 12 weeks.

Population criteria:

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 200 mg tablet [168], 1 pack

10765N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	..	13853.13	Viekira Pak-RBV [VE]

paritaprevir 75 mg + ritonavir 50 mg + ombitasvir 12.5 mg tablet [56] (&) dasabuvir 250 mg tablet [56] (&) ribavirin 600 mg tablet [56], 1 pack

10754B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	..	13853.13	Viekira Pak-RBV [VE]

▪ SOFOSBUVIR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 12 weeks.

sofosbuvir 400 mg tablet, 28

10625F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	..	19297.75	Sovaldi [GI]

▪ SOFOSBUVIR

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 24 weeks.

sofosbuvir 400 mg tablet, 28

10648K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	19297.75	Sovaldi [GI]

▪ ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

▪ ANTINEOPLASTIC AGENTS

ANTIMETABOLITES

Pyrimidine analogues

▪ AZACITIDINE

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Myelodysplastic syndrome

Treatment Phase: Initial treatment

Clinical criteria:

The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR

The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS).

Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:

a. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR

b. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR

c. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR

d. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR

e. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR

f. Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

a. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR

b. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR

c. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR

d. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

The first authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and

(c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and
(d) a copy of the full blood examination report; and
(e) a copy of the pathology report detailing the cytogenetics demonstrating intermediate-2 or high risk disease according to the International Prognostic Scoring System (IPSS); and
(f) a signed patient acknowledgment form.
No more than 3 cycles will be authorised.

Authority required

Chronic Myelomonocytic Leukaemia
Treatment Phase: Initial treatment
Clinical criteria:
The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder.
The first authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and
(c) a copy of the bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia ; and
(d) a copy of the full blood examination report; and
(e) a signed patient acknowledgement.
No more than 3 cycles will be authorised.

Authority required

Acute Myeloid Leukaemia
Treatment Phase: Initial treatment
Clinical criteria:
The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.
The first authority application must be made in writing and must include:
(a) a completed authority prescription form; and
(b) a completed Azacitidine PBS Authority Application - Supporting Information Form; and
(c) a copy of the bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and
(d) a copy of the full blood examination report; and
(e) a signed patient acknowledgement.
No more than 3 cycles will be authorised.

azacitidine 100 mg injection, 1 vial

9597D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
14	2	..	*5172.16	[a] Azadine [RZ]	[a] Vidaza [CJ]

▪ AZACITIDINE

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Myelodysplastic syndrome
Treatment Phase: Continuing treatment
Clinical criteria:
The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR
The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS), AND
Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
Patient must not have progressive disease.
Applications for continuing therapy may be made by telephone.
Up to 6 cycles will be authorised.

Authority required

Chronic Myelomonocytic Leukaemia
Treatment Phase: Continuing treatment
Clinical criteria:
The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder, AND
Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND
Patient must not have progressive disease.
Applications for continuing therapy may be made by telephone.
Up to 6 cycles will be authorised.

Authority required

Acute Myeloid Leukaemia
Treatment Phase: Continuing treatment
Clinical criteria:
The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification, AND
Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND

Patient must not have progressive disease.
Applications for continuing therapy may be made by telephone.
Up to 6 cycles will be authorised.

azacitidine 100 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
9598E	14	5	..	*5172.16	[a] Azadine [RZ]	[a] Vidaza [CJ]

CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

Anthracyclines and related substances

▪ DOXORUBICIN HYDROCHLORIDE-PEGYLATED LIPOSOMAL

Authority required (STREAMLINED)

3348

Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive mucocutaneous involvement

Authority required (STREAMLINED)

3349

Treatment of AIDS-related Kaposi's sarcoma in patients with CD4 cell counts of less than 200 per cubic millimetre and extensive visceral involvement

doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5705G	4	5	..	*1700.96	[a] Caelyx [JC]	[a] Liposomal Doxorubicin SUN [RA]

OTHER ANTINEOPLASTIC AGENTS

Monoclonal antibodies

▪ RITUXIMAB

Note Risk of end-organ damage or mortality includes a minimum of one of the following:
Glomerulonephritis with risk of progression
Risk to sight including scleritis/episcleritis, sudden visual loss, uveitis, retinal changes (vasculitis/thrombosis/exudates/haemorrhage)
Bronchial/subglottic obstruction
Pulmonary haemorrhage
Parenchymal lung disease
Sensory neural hearing loss
Recurrent sinonasal disease requiring recurrent surgical interventions
Meningitis, organic confusion, seizures, stroke, cord lesion, cranial nerve palsy, sensory peripheral neuropathy, motor mononeuritis multiplex

Note Patients could be considered contraindicated, refractory, or unable to tolerate cyclophosphamide for one of the following reasons:
Cyclophosphamide is contraindicated as per the TGA approved Product Information;
Cyclophosphamide is not recommended due to the need to preserve gonad function;
Patient experiences severe toxicity to cyclophosphamide that warrants cessation of treatment;
Patient has life- or organ-threatening deterioration at any time during treatment with cyclophosphamide, where the deterioration is thought to be due to severe uncontrolled active vasculitis;
Commencing a further treatment cycle with cyclophosphamide would exceed the maximum cumulative dose of cyclophosphamide of 25g; or
Patient's condition with this indication is persistent despite at least 3 months therapy with cyclophosphamide.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment.

Authority required

Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)
Treatment Phase: Induction of remission
Clinical criteria:
The treatment must be for the induction of remission, AND
Patient must not have previously received this drug for this condition; OR
Patient must have received this drug for this condition prior to 1 January 2016, AND
The treatment must in combination with glucocorticoids, AND
Patient must be at risk of end-organ damage or mortality, AND

Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.
Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.
This drug is not PBS-subsidised for maintenance of remission

Authority required

Severe active microscopic polyangiitis
Treatment Phase: Induction of remission
Clinical criteria:
The treatment must be for the induction of remission, AND
Patient must not have previously received this drug for this condition; OR
Patient must have received this drug for this condition prior to 1 January 2016, AND
The treatment must in combination with glucocorticoids, AND
Patient must be at risk of end-organ damage or mortality, AND
Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.
Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.
This drug is not PBS-subsidised for maintenance therapy.

Authority required

Severe active granulomatosis with polyangiitis (Wegeners granulomatosis)
Treatment Phase: Re-induction of remission
Clinical criteria:
The treatment must be for the re-induction of remission, AND
Patient must have previously received and responded to this drug for this condition, AND
The treatment must in combination with glucocorticoids, AND
Patient must be at risk of end-organ damage or mortality, AND
Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.
Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.
This drug is not PBS-subsidised for maintenance of remission

Authority required

Severe active microscopic polyangiitis
Treatment Phase: Re-induction of remission
Clinical criteria:
The treatment must be for the re-induction of remission, AND
Patient must have previously received and responded to this drug for this condition, AND
The treatment must in combination with glucocorticoids, AND
Patient must be at risk of end-organ damage or mortality, AND
Patient must be contraindicated, refractory or unable to tolerate cyclophosphamide.
Diagnosis should be made according to the Chapel Hill Consensus Conference Nomenclature of the Vasculitides with anti-neutrophil cytoplasmic antibody (ANCA) positive serology.
This drug is not PBS-subsidised for maintenance therapy.

rituximab 100 mg/10 mL injection, 2 x 10 mL vials

10591K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	759.57	Mabthera [RO]

rituximab 500 mg/50 mL injection, 50 mL vial

10593M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	1898.92	Mabthera [RO]

▪ IMMUNOSTIMULANTS

IMMUNOSTIMULANTS

Colony stimulating factors

▪ FILGRASTIM

Authority required (STREAMLINED)

3357

For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia

Authority required (STREAMLINED)

3358

Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy

Authority required (STREAMLINED)

3359

Mobilisation of peripheral blood progenitor cells, in a normal volunteer, for use in allogeneic transplantation

Authority required (STREAMLINED)

3360
A patient receiving marrow-ablative chemotherapy and subsequent bone marrow transplantation
Authority required (STREAMLINED)

3361
A patient with a non-myeloid malignancy receiving marrow-ablative chemotherapy and subsequent autologous peripheral blood progenitor cell transplantation
Authority required (STREAMLINED)

3368
A patient with chronic cyclic neutropenia (absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))
Authority required (STREAMLINED)

3369
A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned
Authority required (STREAMLINED)

3362
A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned
Authority required (STREAMLINED)

3363
A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned
Authority required (STREAMLINED)

3364
A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned
Authority required (STREAMLINED)

3365
A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned
Authority required (STREAMLINED)

3366
A patient with severe congenital neutropenia (absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, and in whom a bone marrow examination has shown evidence of maturational arrest of the neutrophil lineage)
Authority required (STREAMLINED)

3367
A patient with severe chronic neutropenia (absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, or evidence of neutrophil dysfunction, and, either having experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months, or having recurrent clinically significant infections (a minimum of 3 in the previous 12 months))
Authority required (STREAMLINED)

3370
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia
Authority required (STREAMLINED)

3371
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)
Authority required (STREAMLINED)

3372
A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours
Authority required (STREAMLINED)

3373

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours

Authority required (STREAMLINED)

3374

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma

Authority required (STREAMLINED)

3375

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)

Authority required (STREAMLINED)

3376

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease

Authority required (STREAMLINED)

3377

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma

Authority required (STREAMLINED)

3834

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP)

filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes

5829T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	11	..	*660.18	Nivestim [HH]

filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

1123D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	11	..	*1650.44	TevaGrastim [TB]

filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

5742F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	11	..	*1650.44	Neupogen [AN]

filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

9692D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	11	..	*1650.44	Nivestim [HH]

filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes

2758E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	11	..	*1650.44	Zarzio [SZ]

filgrastim 300 microgram/mL injection, 10 x 1 mL vials

5741E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	11	..	*1650.44	Neupogen [AN]

filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes

5744H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	11	..	*2645.76	Neupogen [AN]

filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes

9694F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	11	..	*2645.76	Nivestim [HH]

filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes

2783L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	11	..	*2645.76	Zarzio [SZ]

filgrastim 480 microgram/0.8 mL injection, 10 x 0.8 mL syringes

1126G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	11	..	*2645.76	TevaGrastim [TB]

filgrastim 480 microgram/1.6 mL injection, 10 x 1.6 mL vials

5743G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	11	..	*2645.76	Neupogen [AN]

▪ LENOGRASTIM

Authority required (STREAMLINED)

3395

Patients with breast cancer receiving standard dose adjuvant chemotherapy who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required (STREAMLINED)

3396

Patients receiving first-line chemotherapy for Hodgkin's disease who have had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required (STREAMLINED)

3392

Mobilisation of peripheral blood progenitor cells to facilitate harvest of such cells for reinfusion into patients with non-myeloid malignancies who have had myeloablative or myelosuppressive therapy

Authority required (STREAMLINED)

3393

Mobilisation of peripheral blood progenitor cells, in normal volunteers, for use in allogeneic transplantation to facilitate harvest of such cells in healthy donors

Authority required (STREAMLINED)

3394

Patients with non-myeloid malignancies receiving marrow-ablative chemotherapy and subsequent peripheral blood progenitor cell or bone marrow transplantation

Authority required (STREAMLINED)

3397

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia

Authority required (STREAMLINED)

3398

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Ewing's sarcoma

Authority required (STREAMLINED)

3399

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours

Authority required (STREAMLINED)

3400

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours

Authority required (STREAMLINED)

3401

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma

Authority required (STREAMLINED)

3402

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin's lymphoma (intermediate or high grade)

Authority required (STREAMLINED)

3403

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in osteosarcoma

Authority required (STREAMLINED)

3404

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin's disease

Authority required (STREAMLINED)

3405

Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in rhabdomyosarcoma

LENOGRASTIM Powder for injection 13,400,000 i.u. (105 micrograms) vial, 10

5787N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	11	..	*973.76	Granocyte 13 [HH]

LENOGRASTIM Powder for injection 33,600,000 i.u. (263 micrograms) vial, 10

5788P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	11	..	*2438.84	Granocyte 34 [HH]

▪ PEGFILGRASTIM

Authority required (STREAMLINED)

3357

For use in a patient undergoing induction and consolidation therapy for acute myeloid leukaemia

Authority required (STREAMLINED)

3362

A patient with breast cancer receiving standard dose adjuvant chemotherapy who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required (STREAMLINED)

3363

A patient receiving chemotherapy for B-cell chronic lymphocytic leukaemia with fludarabine and cyclophosphamide who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required (STREAMLINED)

3364

A patient receiving first-line chemotherapy for Hodgkin disease who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required (STREAMLINED)

3365

A patient receiving chemotherapy for myeloma who has had a prior episode of febrile neutropenia, and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required (STREAMLINED)

3369

A patient with inoperable Stage III, IVa or IVb squamous cell carcinoma of the oral cavity, larynx, oropharynx or hypopharynx receiving neoadjuvant treatment with docetaxel in combination with cisplatin and fluorouracil who has had a prior episode of febrile neutropenia or prolonged severe neutropenia (neutrophil count of less than 1,000 million cells per litre), and for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned

Authority required (STREAMLINED)

3370

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in acute lymphoblastic leukaemia

Authority required (STREAMLINED)

3371

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in breast cancer (adjuvant chemotherapy with docetaxel in combination with an anthracycline and cyclophosphamide)

Authority required (STREAMLINED)

3372

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in germ cell tumours

Authority required (STREAMLINED)

3373

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in infants and children with CNS tumours

Authority required (STREAMLINED)

3374

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in neuroblastoma

Authority required (STREAMLINED)

3375

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in non-Hodgkin lymphoma (aggressive grades; or low grade receiving an anthracycline-containing regimen)

Authority required (STREAMLINED)

3376

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in relapsed Hodgkin disease

Authority required (STREAMLINED)

3377

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in sarcoma

Authority required (STREAMLINED)

3834

A patient being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in Hodgkin disease (first-line chemotherapy with escalated BEACOPP)

pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

9514R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	11	..	1828.75	Neulasta [AN]

Interferons

▪ INTERFERON ALFA-2A

Caution Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Authority required (STREAMLINED)

5042

Chronic Myeloid Leukaemia (CML)

Clinical criteria:

The condition must be Philadelphia chromosome positive.

interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe

5759D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
30	5	..	*849.30	Roferon-A [RO]

interferon alfa-2a 4.5 million units/0.5 mL injection, 0.5 mL syringe

5760E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
30	5	..	*1274.10	Roferon-A [RO]

interferon alfa-2a 6 million units/0.5 mL injection, 0.5 mL syringe

5761F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
30	5	..	*1698.00	Roferon-A [RO]

interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe

5762G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
30	5	..	*2547.30	Roferon-A [RO]

▪ INTERFERON ALFA-2B

Caution Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Authority required (STREAMLINED)

5042

Chronic Myeloid Leukaemia (CML)

Clinical criteria:

The condition must be Philadelphia chromosome positive.

Authority required (STREAMLINED)

4974

Malignant melanoma

Clinical criteria:

The treatment must be as adjunctive therapy to current standard care, AND

Patient must have undergone surgery, AND

The condition must include nodal involvement.

interferon alfa-2b 10 million units/mL injection, 5 x 1 mL vials

5768N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
3	5	..	*1415.04	Intron A [MK]

interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL cartridge

5763H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	..	*339.60	Intron A Redipen [MK]

interferon alfa-2b 18 million units/3 mL injection, 3 mL vial

5766L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
15	5	..	*2547.00	Intron A [MK]

interferon alfa-2b 25 million units/2.5 mL injection, 2.5 mL vial

5767M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	15	5	..	*3537.60	Intron A [MK]

interferon alfa-2b 30 million units/1.2 mL injection, 1.2 mL cartridge

5764J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*566.02	Intron A Redipen [MK]

interferon alfa-2b 60 million units/1.2 mL injection, 1.2 mL cartridge

5765K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1132.02	Intron A Redipen [MK]

▪ INTERFERON GAMMA-1B

Authority required (STREAMLINED)

3385

Treatment of chronic granulomatous disease in patients with frequent and severe infections despite adequate prophylaxis with antimicrobial agents

interferon gamma-1b 2 million units (100 microgram)/0.5 mL injection, 6 x 0.5 mL vials

5769P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	11	..	*2585.72	Imukin [BY]

▪ PEGINTERFERON ALFA-2A

Caution Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Note Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

Authority required (STREAMLINED)

5004

Chronic hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease, AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND

Patient must have a contraindication to ribavirin, AND

The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND

The treatment must be limited to a maximum duration of 48 weeks.

Population criteria:

Patient must be aged 18 years or older, AND

Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes

9515T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*2215.22	Pegasys [RO]

peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes

9516W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*2565.44	Pegasys [RO]

▪ PEGINTERFERON ALFA-2A (&) RIBAVIRIN

Caution Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Chronic hepatitis C infection

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, AND

Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, AND

The treatment must be limited to a maximum duration of 12 weeks.

Population criteria:

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [140 tablets], 1 pack

10664G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	..	1555.40	Pegasys RBV [RO]

peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack

10655T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	..	1635.67	Pegasys RBV [RO]

HSD (Public)

▪ PEGINTERFERON ALFA-2A (&) RIBAVIRIN

Caution Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

Authority required (STREAMLINED)

4184

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease, AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated), AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simeprevir, AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4197

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease, AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and in whom plasma HCV RNA is undetectable by an HCV RNA quantitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4206

Chronic non-genotype 1 hepatitis C infection

Clinical criteria:

The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND

Patient must have compensated liver disease, AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C, AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated), AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C, AND

The treatment must be limited to a maximum duration of 48 weeks, AND

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

Population criteria:

Patient must be aged 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4187

Chronic non-genotype 1 hepatitis C infection

Clinical criteria:

The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND

Patient must have compensated liver disease, AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C, AND

The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis, AND

The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND

The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.

For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.

For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.

peginterferon alfa-2a 135 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack

9524G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*2956.26	Pegasys RBV [RO]

peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [112 tablets], 1 pack

9525H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*2950.26	Pegasys RBV [RO]

peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [140 tablets], 1 pack

9526J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*3110.80	Pegasys RBV [RO]

peginterferon alfa-2a 180 microgram/0.5 mL injection [4 x 0.5 mL syringes] (&) ribavirin 200 mg tablet [168 tablets], 1 pack

9527K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*3271.34	Pegasys RBV [RO]

HSD (Public)

▪ PEGINTERFERON ALFA-2B (&) RIBAVIRIN

Caution Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

Authority required (STREAMLINED)

4184

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease, AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated), AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simeprevir, AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4197

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease, AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and in whom plasma HCV RNA is undetectable by an HCV RNA quantitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4206

Chronic non-genotype 1 hepatitis C infection

Clinical criteria:

The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND

Patient must have compensated liver disease, AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C, AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated), AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C, AND

The treatment must be limited to a maximum duration of 48 weeks, AND

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

Population criteria:

Patient must be aged 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4187

Chronic non-genotype 1 hepatitis C infection

Clinical criteria:

The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND

Patient must have compensated liver disease, AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C, AND

The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis, AND

The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND

The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.

For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.

For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.

peginterferon alfa-2b 120 microgram injection [4 x 120 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack

9536X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*3491.58	Pegatron [MK]

peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack

9538B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*4079.52	Pegatron [MK]

peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [168 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack

9539C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*4079.52	Pegatron [MK]

peginterferon alfa-2b 150 microgram injection [4 x 150 microgram cartridges] (&) ribavirin 200 mg capsule [196 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack

9540D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*4364.48	Pegatron [MK]

peginterferon alfa-2b 80 microgram injection [4 x 80 microgram cartridges] (&) ribavirin 200 mg capsule [140 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack

9531P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*2707.66	Pegatron [MK]

▪ PEGINTERFERON ALFA-2B (&) RIBAVIRIN

Caution Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Ribavirin is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and during the 6 months period after cessation of treatment.

Note Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
(a) a nurse educator/counsellor for patients; and
(b) 24-hour access by patients to medical advice; and
(c) an established liver clinic.

Authority required (STREAMLINED)

4189

Chronic genotype 1 hepatitis C infection

Clinical criteria:

The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND

Patient must have compensated liver disease, AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated), AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C, AND

The treatment must be limited to a maximum duration of 48 weeks, AND

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

Population criteria:

Patient must weigh at least 27 kg, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4198

Chronic genotype 1 hepatitis C infection

Clinical criteria:

The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND

Patient must have compensated liver disease, AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND

The treatment must be limited to a maximum duration of 48 weeks, AND

The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop.

Population criteria:

Patient must weigh at least 27 kg, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4199

Chronic non-genotype 1 hepatitis C infection

Clinical criteria:

The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND

Patient must have compensated liver disease, AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C, AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated), AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C, AND

The treatment must be limited to a maximum duration of 48 weeks, AND

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

Population criteria:

Patient must weigh at least 27 kg, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4192

Chronic non-genotype 1 hepatitis C infection

Clinical criteria:

The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND

Patient must have compensated liver disease, AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C, AND

The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis, AND

The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND

The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must weigh at least 27 kg, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.

For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.

For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.

Authority required (STREAMLINED)

4184

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease, AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated), AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin without an NS3 protease inhibitor, or, in triple combination therapy with boceprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with telaprevir; OR

Patient must have received prior treatment with interferon alfa or peginterferon alfa for hepatitis C if using peginterferon and ribavirin in triple combination therapy with simeprevir, AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 36 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who were prior treatment partial responders or relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 12; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who were prior treatment relapsers and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir who: (i) were prior treatment null responders; or (ii) were prior treatment partial responders or relapsers and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 12; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (iii) have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir who: (i) were prior treatment partial or null responders; or (ii) were prior treatment relapsers and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic genotype 1 hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4197

Chronic genotype 1 hepatitis C infection

Clinical criteria:

Patient must have compensated liver disease, AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with telaprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 4 and 12; OR

The treatment must be limited to a maximum duration of 28 weeks in patients using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is undetectable by an HCV RNA qualitative assay at weeks 8 and 24; OR

The treatment must be limited to a maximum duration of 24 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and in whom plasma HCV RNA is undetectable by an HCV RNA quantitative assay at week 4; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin without an NS3 protease inhibitor; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with boceprevir and in whom plasma HCV RNA is detectable by an HCV RNA qualitative assay at week 8, and undetectable by an HCV RNA qualitative assay at week 24; or (ii) using peginterferon and ribavirin in triple combination therapy with boceprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients: (i) using peginterferon and ribavirin in triple combination therapy with telaprevir and for whom the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is detectable but less than or equal to 1000 IU/mL; or (ii) using peginterferon and ribavirin in triple combination therapy with telaprevir who have hepatic cirrhosis; OR

The treatment must be limited to a maximum duration of 48 weeks in patients using peginterferon and ribavirin in triple combination therapy with simeprevir and for whom the results of an HCV RNA qualitative assay at week 4 show that the plasma HCV RNA is detectable but less than 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin without an NS3 protease inhibitor unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with boceprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than 1000 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with telaprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if the results of an HCV RNA quantitative assay at week 4 show that the plasma HCV RNA is greater than or equal to 25 IU/mL, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 12, AND

The treatment must cease in patients using peginterferon and ribavirin in combination with simeprevir if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients using peginterferon and ribavirin without an NS3 protease inhibitor who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4206

Chronic non-genotype 1 hepatitis C infection

Clinical criteria:

The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND

Patient must have compensated liver disease, AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C, AND

Patient must have failed prior treatment with interferon based therapies (non-pegylated or pegylated), AND

Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C, AND

The treatment must be limited to a maximum duration of 48 weeks, AND

The treatment must cease if HCV RNA is detectable by an HCV RNA qualitative assay at week 12.

Population criteria:

Patient must be aged 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4187

Chronic non-genotype 1 hepatitis C infection

Clinical criteria:

The treatment must be the sole PBS-subsidised treatment for hepatitis C, AND

Patient must have compensated liver disease, AND

Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, AND

The condition must be genotype 2, 3, 4, 5 or 6 hepatitis C, AND

The treatment must be limited to a maximum duration of 24 weeks for patients with genotype 2 or 3 hepatitis C without hepatic cirrhosis or bridging fibrosis; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 4, 5 or 6 hepatitis C; OR

The treatment must be limited to a maximum duration of 48 weeks for patients with genotype 2 or 3 hepatitis C with hepatic cirrhosis or bridging fibrosis, AND

The treatment must cease in patients with genotype 4, 5, or 6 hepatitis C unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) shows that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, AND

The treatment must cease in patients eligible for 48 weeks of treatment if HCV RNA is detectable by an HCV RNA qualitative assay at week 24.

Population criteria:

Patient must be aged 18 years or older, AND

Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age.

Treatment criteria:

Must be treated in an accredited treatment centre.

Evidence of chronic hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

For patients with genotype 4, 5, or 6 who are viral negative at week 12, an HCV RNA qualitative assay at week 24 is unnecessary.

For patients with genotype 2 or 3 without cirrhosis, an HCV RNA assay at week 12 is unnecessary because of the high likelihood of early viral response by week 12.

For patients who are eligible for 24 weeks of treatment, a maximum of 2 repeats may be prescribed.

For patients who are eligible for 48 weeks of treatment, a maximum of 5 repeats may be prescribed.

peginterferon alfa-2b 100 microgram injection [4 x 100 microgram cartridges] (&) ribavirin 200 mg capsule [112 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack

9534T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*3099.62	Pegatron [MK]

peginterferon alfa-2b 50 microgram injection [4 x 50 microgram cartridges] (&) ribavirin 200 mg capsule [112 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack

9529M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*2119.74	Pegatron [MK]

peginterferon alfa-2b 80 microgram injection [4 x 80 microgram cartridges] (&) ribavirin 200 mg capsule [84 capsules] (&) inert substance diluent [4 x 0.5 mL cartridges], 1 pack

9530N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*2422.72	Pegatron [MK]

Other immunostimulants

▪ PLERIXAFOR

Note Applications for increased maximum quantities will only be authorised for patients with body weight greater than 100 kg.

Authority required (STREAMLINED)

4549

Mobilisation of haematopoietic stem cells

Clinical criteria:

The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF), AND

Patient must have lymphoma; OR

Patient must have multiple myeloma, AND

Patient must require autologous stem cell transplantation, AND

Patient must have failed previous stem cell collection; OR

Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; OR

Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

plerixafor 24 mg/1.2 mL injection: subcutaneous infusion, 1.2 mL vial

10083Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	1	..	6991.00	Mozobil [GZ]

IMMUNOSUPPRESSANTS

IMMUNOSUPPRESSANTS

Selective immunosuppressants

ABATACEPT

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis, AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND

Patient must not have failed previous PBS-subsidised treatment with this drug for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

Patient must not receive more than 16 weeks of treatment under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a

further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND

Patient must not receive more than 16 weeks of treatment under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 4 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to a treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New

baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have demonstrated an adequate response to treatment with this drug, AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists

(adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

abatacept 250 mg injection, 1 vial

5605B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	359.41	Orencia [BQ]

▪ ALEMTUZUMAB

Note Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

Note Special Pricing Arrangements apply.

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4829

Multiple sclerosis

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug, AND

Patient must not show continuing progression of disability while on treatment with this drug, AND

Patient must not receive more than one PBS-subsidised treatment per year, AND

The treatment must be as monotherapy, AND

Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

Treatment criteria:

Must be treated by a neurologist.

alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial

10232M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
3	..	..	*34182.00	Lemtrada [GZ]

▪ ALEMTUZUMAB

Note Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.
Note Special Pricing Arrangements apply.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4834

Multiple sclerosis

Treatment Phase: Initial

Clinical criteria:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, AND

The treatment must be as monotherapy, AND

Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years, AND

Patient must be ambulatory (without assistance or support).

Treatment criteria:

Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.

alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial

10228H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
5	..	..	*56970.00	Lemtrada [GZ]

▪ ECULIZUMAB

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 4 repeats, according to the specified dosage in the approved Product Information (PI).
Note Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.
Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment – Balance of Supply

Clinical criteria:

Patient must have received PBS-subsidised initial supply of eculizumab for this condition, AND

Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample, AND

Patient must not receive more than 20 weeks supply under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

ADAMTS-13 activity result must have been submitted to the Department of Human Services. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for Initial Treatment, ADAMTS-13 activity must have been measured 1-2 weeks following the last plasma exchange or infusion, and must have been submitted to the Department of Human Services within 27 days of commencement of eculizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the two weeks prior to collection of the ADAMTS-13 assay must also have been provided to Department of Human Services.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

eculizumab 300 mg/30 mL injection, 30 mL vial

10190H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	4	..	5937.50	Soliris [XI]

▪ ECULIZUMAB

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment, according to the specified dosage in the approved Product Information (PI)

Note Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)
> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use
> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have active and progressing thrombotic microangiopathy (TMA), AND

Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than 30x10^9/L and a serum creatinine of greater than 150 mol/L, AND

Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days, AND

Patient must have clinical features of active organ damage or impairment, AND

Patient must not receive more than 4 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Evidence of active and progressing TMA is defined by the following:

(1) a platelet count of less than 150x10^9/L; and evidence of two of the following:

(i) presence of schistocytes on blood film;

(ii) low or absent haptoglobin;

(iii) lactate dehydrogenase (LDH) above normal range;

OR

(2) tissue biopsy confirming TMA in patients who do not have evidence of platelet consumption and haemolysis; AND

(3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one of the following:

(i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or

(ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or

(iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or

(iv) a renal biopsy

(b) onset of TMA-related neurological impairment;

(c) onset of TMA-related cardiac impairment;

(d) onset of TMA-related gastrointestinal impairment;

(e) onset of TMA-related pulmonary impairment

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form - Initial PBS-subsidised eculizumab treatment; and

(3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and

(4) A copy of a current Certificate of vaccination; and

(5) A measurement of body weight at the time of application; and

(6) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay; and

(7) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 1-2 weeks following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to the Department of Human Services within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under Initial treatment - balance of supply; and

(8) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days; and

(9) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within one month of application; and

(10) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.

eculizumab 300 mg/30 mL injection, 30 mL vial

10191J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	5937.50	Soliris [XI]

▪ ECULIZUMAB

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 6 repeats, according to the specified dosage in the approved Product Information (PI).

Note Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)
> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use
> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Note For patients who have received continuing treatment with PBS-subsidised eculizumab prior to 1 January 2016, this restriction is limited to 28 weeks of therapy.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended initial treatment - Assessment phase

Clinical criteria:

Patient must have received treatment under the initial restriction with PBS subsidised eculizumab for this condition, AND

Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, AND

Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, AND

Patient must not receive more than 56 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure .

A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

A maximum of up to 56 weeks of treatment is allowed under this restriction, however an application must be submitted at 6 months, 12 months, 18 months and 24 months following commencing PBS-subsidised eculizumab.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Extended Initial treatment; and

(3) A copy of a current Certificate of vaccination; and

(4) A measurement of body weight at the time of application; and

(5) An identified genetic mutation, if applicable; and

(6) A family history of aHUS, if applicable; and

(7) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and

(8) A history of kidney transplant, if applicable, (especially if required due to aHUS); and

(9) An inclusion of the individual consequences of recurrent disease, if applicable; and

(10) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and

(11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(12) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

eculizumab 300 mg/30 mL injection, 30 mL vial

10525Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	6	..	5937.50	Soliris [XI]

▪ ECULIZUMAB

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis)
> Vaccinate patients with a meningococcal vaccine at least 2 weeks prior to receiving the first dose of eculizumab; revaccinate according to current medical guidelines for vaccine use
> Patients less than 2 years of age and those who are treated with eculizumab less than 2 weeks after receiving a meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Written applications for authority to prescribe must be submitted to Department of Human Services. Human Services will then contact the prescriber by telephone.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have received treatment under Extended Initial restriction with PBS subsidised eculizumab for this condition, AND

Patient must have demonstrated on-going treatment response of PBS-subsidised eculizumab treatment for this condition, AND

Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, AND

Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure .

A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and

(3) A copy of a current Certificate of vaccination; and

(4) A measurement of body weight at the time of application; and

(5) An identified genetic mutation, if applicable; and

(6) A family history of aHUS, if applicable; and

(7) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and

(8) A history of kidney transplant if applicable (especially if required due to aHUS); and

(9) An inclusion of the individual consequences of recurrent disease, if applicable; and

(10) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and

(11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(12) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Note Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended Continuing treatment

Clinical criteria:

Patient must have received treatment under the Continuing treatment with PBS-subsidised eculizumab for this condition, AND

Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition, AND

Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, AND

Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40%; OR

Patient must have severe TMA-related neurological impairment; OR

Patient must have severe TMA-related gastrointestinal impairment; OR

Patient must have severe TMA-related pulmonary impairment; OR

Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 ml/min), AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure . A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and

(3) A copy of a current Certificate of vaccination; and

(4) A measurement of body weight at the time of application; and

(5) An identified genetic mutation, if applicable; and

(6) A family history of aHUS, if applicable; and

(7) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and

(8) A history of kidney transplant, if applicable (especially if required due to aHUS); and

(9) An inclusion of the individual consequences of recurrent disease; and

(10) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment; and

(11) Evidence that the patient has had a treatment response including haematological results of no more than 1 month old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 month old at the time of application; and

(12) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(13) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Note Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have demonstrated treatment response to previous treatment with PBS-subsidised eculizumab for this condition, AND

Patient must not have ever experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, AND

Patient must have the following clinical conditions:(i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal;AND(ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count <150 x 10^9/L);OR(iii) TMA-related organ impairment including on recent biopsy, AND

Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure . A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form(s); and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Recommencement of treatment; and

(3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and

(4) A copy of a current Certificate of vaccination; and

(5) A measurement of body weight at the time of application, and

(6) An identified genetic mutation, if applicable; and

(7) A family history of aHUS if applicable; and

(8) A history of multiple episodes of aHUS following the treatment break, if applicable; and

(9) A history of kidney transplant if applicable (especially if required due to aHUS); and

(10) An inclusion of the individual consequences of recurrent disease; and

(11) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;

(12) Evidence that the patient has had a treatment response to their previous treatment with eculizumab; and

(13) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(14) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Note Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note A raise in LDH alone is not a sufficient reason to re-commence eculizumab, but thrombocytopenia with one marker of haemolysis (such as raised LDH, presence of schistocytes, or low/absence of haptoglobin) is an accepted reason to consider re-commencement of eculizumab treatment.

Note Kidney transplantation/dialysis is not a contraindication to recommencement of eculizumab treatment.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing recommencement of treatment

Clinical criteria:

Patient must have received treatment under Recommencement of treatment restriction with PBS-subsidised eculizumab for this condition, AND

Patient must have demonstrated ongoing treatment response to the previous 24 weeks of PBS-subsidised eculizumab for this condition, AND

Patient must not have experienced treatment failure with eculizumab including PBS-subsidised eculizumab for this condition, AND

Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure . A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for Continuing treatment; and

(3) A copy of a current Certificate of vaccination; and

(4) A measurement of body weight at the time of application; and

(5) An identified genetic mutation, if applicable; and

(6) A family history of aHUS, if applicable; and

(7) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable; and

(8) A history of kidney transplant if applicable (especially if required due to aHUS); and

(9) An inclusion of the individual consequences of recurrent disease, if applicable; and

(10) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; and

(11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and

(12) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Note Applications for treatment with eculizumab where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Authority required

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Grandfather eculizumab patient

Clinical criteria:

Patient must have had documented history of active and progressing thrombotic microangiopathy (TMA), AND

Patient must have had documented an ADAMTS-13 activity level consistent with a diagnosis of aHUS, AND

Patient must have received treatment with eculizumab for this condition prior to 1 December 2014, AND

Patient must have received treatment with eculizumab within the last 6 months at the time of application, AND

Patient must have demonstrated on-going treatment response as specified in the Extended Initial treatment criteria for PBS-subsidised treatment with eculizumab for this condition, if the patient has received adequate therapy in order to demonstrate response, AND

Patient must not have experienced treatment failure with eculizumab for this condition as specified in the Extended Initial treatment criteria for PBS-subsidised treatment with eculizumab for this condition, AND

Patient must have clinical features of active organ damage or impairment at the time of a diagnosis of aHUS episode that required treatment with eculizumab, AND

Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist, or, must be in consultation with a paediatric nephrologist, a nephrologist, a paediatric haematologist or a haematologist.

Evidence of active and progressing TMA is defined by the following:

(1) a platelet count of less than 150x10^9/L; and evidence of two of the following:

(i) presence of schistocytes on blood film;

(ii) low or absent haptoglobin;

(iii) lactate dehydrogenase (LDH) above normal range;

OR

(2) tissue biopsy confirming TMA in patients who do not have evidence of platelet consumption and haemolysis; AND

(3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one of the following:

(i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or

(ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or

(iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or

(iv) a renal biopsy

(b) onset of TMA-related neurological impairment;

(c) onset of TMA-related cardiac impairment;

(d) onset of TMA-related gastrointestinal impairment;

(e) onset of TMA-related pulmonary impairment

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: platelet count, haptoglobin, and LDH; AND

(2) One of the following:

a) An increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with eculizumab or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure . A treatment failure is defined as a patient who is:

(1) dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) on dialysis and has been on dialysis for 4 months of the previous 6 months while receiving PBS-subsidised eculizumab and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include:

(1) A completed authority prescription form; and

(2) A completed aHUS eculizumab Authority Application Supporting Information Form for initial PBS-subsidised eculizumab treatment; and

(3) A signed patient acknowledgement or an acknowledgement signed by a parent or authorised guardian, if applicable; and
(4) A copy of a current Certificate of vaccination; and
(5) A measurement of body weight at the time of application; and
(6) The result of ADAMTS-13 activity on a blood sample at the time this condition was diagnosed; and
(7) An identified genetic mutation, if applicable; and
(8) A family history of aHUS, if applicable; and
(9) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable; and
(10) A history of kidney transplant if applicable (especially if required due to aHUS); and
(11) An inclusion of the individual consequences of recurrent disease; and
(12) Evidence that the patient has previously received treatment with eculizumab for this condition within the last 6 months at the time of application; and
(13) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application; or clinical reasons to justify the commencing of treatment with PBS-subsidised eculizumab; and
(14) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved; and
(15) A confirmed negative STEC (Shiga toxin-producing E.Coli) result if available at the time of diagnosis; or evidence that the diagnosis was not associated with an infection; and
(16) Where available in the week prior to commencing eculizumab results demonstrating:
(a) a platelet count of less than 150 x10^9/L; and evidence of two of the following:
(i) presence of schistocytes on blood film;
(ii) low or absent haptoglobin;
(iii) lactate dehydrogenase (LDH) above normal range;
OR
(b) tissue biopsy confirming TMA in patients who do not have evidence of platelet consumption and haemolysis; AND
(c) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:
(a) kidney impairment as demonstrated by one of the following:
(i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or
(ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or
(iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or
(iv) a renal biopsy
(b) onset of TMA-related neurological impairment;
(c) onset of TMA-related cardiac impairment;
(d) onset of TMA-related gastrointestinal impairment;
(e) onset of TMA-related pulmonary impairment; and
(17) Where available within one month prior to commencement of eculizumab, evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records.
This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

eculizumab 300 mg/30 mL injection, 30 mL vial

10183Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	5937.50	Soliris [XI]

▪ EVEROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

5795

Management of renal allograft rejection
Treatment Phase: Management (initiation, stabilisation and review of therapy)
Clinical criteria:
Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND
The treatment must be under the supervision and direction of a transplant unit.

Authority required (STREAMLINED)

5554

Management of cardiac allograft rejection
Treatment Phase: Management (initiation, stabilisation and review of therapy)
Clinical criteria:
Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, AND
The treatment must be under the supervision and direction of a transplant unit.

everolimus 1 mg tablet, 60

5737Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	4	5	..	*3652.56	Certican [NV]

everolimus 250 microgram tablet, 60

5738B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*456.58	Certican [NV]

everolimus 500 microgram tablet, 60

5739C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*913.14	Certican [NV]

everolimus 750 microgram tablet, 60

5740D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	4	5	..	*2739.44	Certican [NV]

▪ MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

5795

Management of renal allograft rejection
Treatment Phase: Management (initiation, stabilisation and review of therapy)
Clinical criteria:
Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND
The treatment must be under the supervision and direction of a transplant unit.

Authority required (STREAMLINED)

5554

Management of cardiac allograft rejection
Treatment Phase: Management (initiation, stabilisation and review of therapy)
Clinical criteria:
Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, AND
The treatment must be under the supervision and direction of a transplant unit.

mycophenolate mofetil 1 g/5 mL oral liquid: powder for, 165 mL

9500B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*489.02	CellCept [RO]

mycophenolate mofetil 500 mg tablet, 50

9502D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*428.88	[a] APO-Mycophenolate [TX]	[a] CellCept [RO]
					[a] Ceptolate [AF]	[a] Mycophenolate AN [EA]
					[a] Mycophenolate Sandoz [SZ]	[a] Pharmacor Mycophenolate 500 [CR]

▪ MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Note Management includes initiation, stabilisation and review of therapy as required.

Authority required (STREAMLINED)

4084

Prophylaxis of renal allograft rejection
Treatment Phase: Management
Clinical criteria:
The treatment must be under the supervision and direction of a transplant unit.

Authority required (STREAMLINED)

4095

WHO Class III, IV or V lupus nephritis
Treatment Phase: Management
Clinical criteria:
The condition must be proven by biopsy.
Treatment criteria:
Must be treated by a nephrologist or in consultation with a nephrologist.
The name of the consulting nephrologist must be included in the patient medical records.

mycophenolate 180 mg tablet: enteric, 120

9503E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*171.58	Myfortic [NV]

mycophenolate 360 mg tablet: enteric, 120

9504F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	..	*343.12	Myfortic [NV]

▪ MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Note For item codes 9501C and 1839T, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution

Authority required (STREAMLINED)

5653

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND

The treatment must be under the supervision and direction of a transplant unit.

Authority required (STREAMLINED)

5600

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, AND

The treatment must be under the supervision and direction of a transplant unit.

mycophenolate Capsule 250 mg, 50

1839T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
12	5	..	*429.00	[a] Ceptolate [AF]

mycophenolate mofetil 250 mg capsule, 100

9501C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
6	5	..	*429.00	[a] APO-Mycophenolate [TX]	[a] CellCept [RO]
				[a] Mycophenolate Sandoz [SZ]	[a] Pharmacor Mycophenolate 250 [CR]

▪ NATALIZUMAB

Caution Progressive multifocal leukoencephalopathy has been reported with this drug.

Authority required (STREAMLINED)

6043

Clinically definite relapsing-remitting multiple sclerosis

Clinical criteria:

The treatment must be as monotherapy, AND

Patient must be ambulatory (without assistance or support), AND

Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years, AND

The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; OR

Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a neurologist.

The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.

Treatment with this drug must cease if there is continuing progression of disability whilst the patient is being treated with this drug.

For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug.

Neurologists prescribing natalizumab under the PBS listing must be registered with the Tysabri Australian Prescribing Program.

natalizumab 300 mg/15 mL injection, 15 mL vial

9505G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	1489.64	Tysabri [BD]

▪ SIROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

5795

Management of renal allograft rejection
Treatment Phase: Management (initiation, stabilisation and review of therapy)
Clinical criteria:
Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND
The treatment must be under the supervision and direction of a transplant unit.

sirolimus 1 mg tablet, 100

9549N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*1374.32	Rapamune [PF]

sirolimus 1 mg/mL oral liquid, 60 mL

9550P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*889.20	Rapamune [PF]

sirolimus 2 mg tablet, 100

9548M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*2748.68	Rapamune [PF]

sirolimus 500 microgram tablet, 100

9747B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*687.18	Rapamune [PF]

HSD (Public)

▪ VEDOLIZUMAB

Note Special Pricing Arrangements apply.

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of infliximab and vedolizumab for adult patients with ulcerative colitis.
Patients are eligible for PBS-subsidised treatment with either infliximab or vedolizumab at any one time.
From 1 August 2015, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised infliximab or vedolizumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with infliximab or vedolizumab while they continue to show a response to therapy.
A patient who received PBS-subsidised infliximab or vedolizumab treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised infliximab or vedolizumab more than twice.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised infliximab or vedolizumab treatment in the most recent cycle to the date of the first application for initial treatment with infliximab or vedolizumab under the new treatment cycle.
A patient who has failed fewer than 3 trials of either infliximab or vedolizumab in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of either infliximab or vedolizumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
(1) How to prescribe PBS-subsidised infliximab or vedolizumab therapy after 1 August 2015.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised treatment with infliximab or vedolizumab in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) infliximab or vedolizumab therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with infliximab or vedolizumab following a break in PBS-subsidised therapy with the same agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 14 weeks of therapy.
From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised treatment up to 12 weeks after the first dose (6 weeks following the third dose), and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.
For second and subsequent courses of PBS-subsidised infliximab or vedolizumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with infliximab or vedolizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services

no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate infliximab or vedolizumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy.
A patient may trial the alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with infliximab or vedolizumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to the alternate infliximab or vedolizumab therapy should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Mayo clinic score or partial Mayo clinic score submitted with the first authority application for infliximab or vedolizumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised infliximab or vedolizumab therapy of at least 5 years, must requalify for initial treatment with respect to the scores of disease severity.
Patients must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine, 6-mercaptopurine or tapered course of oral steroids (unless intolerance develops necessitating permanent treatment withdrawal) for a minimum of 3 consecutive months immediately prior to the time the Mayo score or PUCAI score is measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab or infliximab.
A patient who commenced treatment with vedolizumab for moderate to severe ulcerative colitis prior to 1 August 2015 or infliximab prior to 1 December 2014 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment (new patient – Initial 1)

Clinical criteria:

Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal, AND

Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR

Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR

Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, AND

Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR

Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), AND

Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 1 month old at the time of application.

Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose for patients administered doses at weeks 0, 2 and 6 (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

Patients must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Note Details of accepted toxicities including severity can be found on the Department of Human Services website at www.humanservices.gov.au.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug for this condition, AND

Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug, AND

Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

Note No applications for increased repeats will be authorised.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial PBS-subsidised treatment (Grandfather patient)

Clinical criteria:

Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 August 2015, AND

Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing treatment with this drug; OR

Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing treatment with this drug; OR

Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing treatment with this drug; OR

Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing treatment with this drug; OR

Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced treatment with this drug where a Mayo clinic or partial Mayo clinic baseline assessment is not available; OR

Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced treatment with this drug where a Mayo clinic or partial Mayo clinic baseline assessment is not available, AND

Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug, AND

Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

Patient must be 18 years of age or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and baseline Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the date of commencement of this drug; and

(iii) the signed patient acknowledgement.

The current Mayo clinic or partial Mayo clinic assessment must be no more than 1 month old at the time of application. The baseline assessment must be from immediately prior to commencing treatment with this drug. Where a baseline assessment is not available the prescriber must contact the Department of Human Services to discuss.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note The patient must have signed a patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

Note No applications for increased repeats will be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Change or Re-commencement of treatment after a break in therapy (Initial 2)

Clinical criteria:

Patient must have previously been issued with an authority prescription for infliximab or vedolizumab for this condition in this treatment cycle, AND

Patient must not have failed PBS-subsidised therapy with vedolizumab for this condition more than once in the current treatment cycle, AND

Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses of treatment may be requested by telephone by contacting the Department of Human Services.

Note No applications for increased repeats will be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR

Patient must have received insufficient therapy with this drug to complete 24 weeks of treatment under the Initial PBS-subsidised treatment restriction for patients who had previously received non-PBS subsidised treatment (Grandfathered patient), AND

The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing or Grandfathered patients), AND

Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

Note Written applications for authority approval for sufficient therapy to complete the balance of supply should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

vedolizumab 300 mg injection, 1 x 300 mg vial

10384M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	3105.19	Entyvio [TK]

▪ VEDOLIZUMAB

Note No applications for increased maximum quantities will be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Special Pricing Arrangements apply.

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the

following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab).
Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.
From 1 August 2015, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised TNF-alfa antagonist or vedolizumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist or vedolizumab while they continue to show a response to therapy.
A patient who received PBS-subsidised TNF-alfa antagonist or vedolizumab treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist or vedolizumab more than twice.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist or vedolizumab treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist or vedolizumab under the new treatment cycle.
A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised TNF-alfa antagonist or vedolizumab therapy after 1 August 2015.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised therapy with TNF-alfa antagonist or vedolizumab in this treatment cycle and wishes to commence such therapy (new patients); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy or vedolizumab and wishes to trial an alternate agent (recommencement) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist or vedolizumab following a break in PBS-subsidised therapy with that agent (change or re-commencement).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab and 14 weeks of therapy for vedolizumab.
From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.
For second and subsequent courses of PBS-subsidised TNF-alfa antagonist or vedolizumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific TNF-alfa antagonist or vedolizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist or vedolizumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist or vedolizumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist or vedolizumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.
(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist or vedolizumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.
A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment (new patient – initial 1)

Clinical criteria:

Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, AND

Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR

Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, AND

Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR

Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR

Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug, AND

Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment, AND

Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR

Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, AND

Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR

Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR

Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

Note This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Authority required

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

Clinical criteria:

Patient must have a documented history of severe Crohn disease, AND

Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, AND

Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle, AND

Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Authority required

Severe Crohn disease

Treatment Phase: Initial PBS-subsidised treatment (Grandfather)

Clinical criteria:

Patient must have a documented history of severe Crohn disease, AND

Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 August 2015, AND

Patient must have had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with this drug; OR

Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR

Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, AND

Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR

Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, AND

Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply

restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR

Patient must have received insufficient therapy with this drug to complete 24 weeks of treatment under the Initial PBS-subsidised treatment restriction for patients who had previously received non-PBS subsidised treatment (Grandfathered patient), AND

The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing or Grandfathered patients), AND

Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Note Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe Crohn disease, AND

Patient must have previously been issued with an authority prescription for this drug for this condition, AND

Patient must have demonstrated or sustained an adequate response to treatment with this drug, AND

Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment, AND

Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR

Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests and diagnostic imaging studies, must be made within 1 month of the date of application.

If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

vedolizumab 300 mg injection, 1 x 300 mg vial

10390W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	3105.19	Entyvio [TK]

Tumor necrosis factor alpha (TNF-) inhibitors

▪ ADALIMUMAB

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

Clinical criteria:

Patient must have severe active juvenile idiopathic arthritis, AND

Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR

Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, AND

Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR

Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial adalimumab after a minimum

of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to

respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis, AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, AND

Patient must not have failed PBS-subsidised therapy with adalimumab for this condition in the current treatment cycle, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with adalimumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.

From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.

A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline

measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

Clinical criteria:

Patient must have received insufficient adalimumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient adalimumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis, AND

Patient must have demonstrated an adequate response to treatment with adalimumab, AND

Patient must have received adalimumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide sufficient for two doses. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
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Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is

important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:

Patient must have received insufficient adalimumab therapy under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes

9661L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	1548.50	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

9663N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	1548.50	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9662M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	1548.50	Humira [VE]

▪ ETANERCEPT

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

Clinical criteria:

Patient must have severe active juvenile idiopathic arthritis, AND

Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR

Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, AND

Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR

Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial etanercept after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis, AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, AND

Patient must not have failed PBS-subsidised therapy with etanercept for this condition in the current treatment cycle, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with etanercept in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply

Clinical criteria:

Patient must have received insufficient etanercept therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient etanercept therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis, AND

Patient must have demonstrated an adequate response to treatment with etanercept, AND

Patient must have received etanercept as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:

Patient must have received insufficient etanercept therapy under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

5735W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	1548.51	Enbrel [PF]

ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

5733R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	1548.51	Enbrel [PF]

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

5734T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	774.25	Enbrel [PF]

▪ INFLIXIMAB

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

4524

Acute severe ulcerative colitis

Clinical criteria:

Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application, AND

Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; OR

Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below, AND

Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital.

Population criteria:

Patient must be 6 years of age or older.

Treatment criteria:

Must be treated by a gastroenterologist; OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology].

For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where:

(i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L

(ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood.

For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours.

At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient's medical records.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

infliximab 100 mg injection, 1 vial

10067W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	1	..	*2874.25	[a] Inflectra [HH]	[a] Remicade [JC]

▪ INFLIXIMAB

Note Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.
Written applications for authority to prescribe infliximab should be forwarded to:
Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for patients with complex refractory fistulising Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 April 2011 is considered to be in their first cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats. The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.

A patient who commenced treatment with adalimumab for complex refractory fistulising Crohn disease prior to 4 November 2010 or infliximab prior to 1 March 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Initial 1

Initial treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and

(b) has an externally draining enterocutaneous or rectovaginal fistula; and

(c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6 will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Authority required

Initial 2

Change or re-commencement of treatment of complex refractory FISTULISING CROHN DISEASE.

Initial PBS-subsidised treatment with infliximab of complex refractory fistulising Crohn disease by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with complex refractory fistulising Crohn disease who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and

(c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and

(ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment

Authority required

Initial 3 (grandfather)

Initial PBS-subsidised treatment of complex refractory FISTULISING CROHN DISEASE in a patient who has previously received non-PBS-subsidised therapy with infliximab.

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who satisfies the following criteria:

(a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with infliximab prior to 1 March 2010; and

(b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with infliximab; and

(c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) is receiving treatment with infliximab at the time of application; and

(e) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes the following:

(i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and

(ii) a signed patient acknowledgement.

The current fistula assessment must be no more than 1 month old at the time of application.

The baseline fistula assessment must be from immediately prior to commencing treatment with infliximab.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only

Authority required

Continuing treatment of complex refractory FISTULISING CROHN DISEASE.

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

(a) has a documented history of complex refractory fistulising Crohn disease; and

(b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Authority applications must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The fistula assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

An assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

infliximab 100 mg injection, 1 vial

9654D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	574.85	[a] Inflectra [HH]	[a] Remicade [JC]

▪ INFLIXIMAB

Note Special Pricing Arrangements apply.

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any one time.

For paediatric patients with Crohn disease, infliximab is PBS-subsidised for moderate to severe disease while adalimumab is PBS-subsidised for severe disease.

From 1 August 2015, under the PBS, patients commencing on adalimumab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to infliximab. Patients on infliximab will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist but will need to meet a PCDAI score of greater than or equal to 40 when swapping to adalimumab.

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised

therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.
From 1 August 2015, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be submitted to theDepartment of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.
For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient with severe disease may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.
Patients on infliximab may swap to adalimumab within the same treatment cycle provided that their disease severity has progressed to severe disease (i.e. they have a current PCDAI score of 40 or more).
A patient cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the PCDAI submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.
Patients must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months immediately prior to the time the PCDAI score is measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab.
A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab will be assessed under the continuing treatment restriction.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a continuing patient.

Authority required

Moderate to severe Crohn disease

Treatment Phase: Initial treatment (new paediatric patient) of Crohn disease in a paediatric patient assessed by PCDAI (Initial 1)

Clinical criteria:

Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist, consultant physician, paediatrician or specialist paediatric gastroenterologist, AND

Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR

Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, AND

Patient must have, at the time of application, disease severity considered to be moderate to severe as demonstrated by a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment and which is no more than 1 month old at the time of application.

Population criteria:

Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician or a specialist paediatric gastroenterologist; OR

Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription forms; and

(b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition; and

(iii) the signed patient or guardian acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Human Services website (www.humanservices.gov.au).

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe Crohn disease

Treatment Phase: Change or re-commencement of treatment of Crohn disease in a paediatric patient assessed by PCDAI (Initial 2)

Clinical criteria:

Patient must have a documented history of moderate to severe Crohn disease, AND

Patient must in this treatment cycle, have received prior PBS-subsidised treatment with this drug for this condition; OR

Patient must in this treatment cycle, have received prior PBS-subsidised treatment with adalimumab for this condition, AND

Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

Population criteria:

Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician or a specialist paediatric gastroenterologist; OR

Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed paediatric Crohn Disease PBS Authority Application -Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and

(ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe Crohn disease

Treatment Phase: Continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

Clinical criteria:

Patient must have a documented history of moderate to severe Crohn disease, AND

Patient must have previously been issued with an authority prescription for this drug for this condition, AND

Patient must have demonstrated an adequate response to treatment with this drug as defined as a reduction in PCDAI Score by at least 15 points as compared to baseline and a total of PCDAI score of 30 points or less with the PCDAI assessment being no more than 1 month old at the time of application.

Population criteria:

Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician or a specialist paediatric gastroenterologist; OR

Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Department of Human Services website (www.humanservices.gov.au)] which includes the following:

(i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with this drug, a PCDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment in courses of up to 24 weeks providing they continue to sustain the response.

A maximum of 24 weeks treatment will be authorised under this criterion.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) and authorised through the 'Balance of Supply' treatment phase PBS restriction.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe Crohn disease

Treatment Phase: Balance of supply for a paediatric patient

Clinical criteria:

Patient must have received insufficient therapy with this drug under Initial 1 (new patient or patient recommencing treatment after break of more than 5 years) or Initial 2 (change or recommencement of treatment after a break of less than 5 years) or Continuing treatment to complete the maximum duration of treatment specified in the relevant treatment phase, AND

The treatment must provide no more than the balance of up to 3 doses or 2 repeats.

Treatment criteria:

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a gastroenterologist (code 87) or a consultant physician [internal medicine specialising in gastroenterology (code 81)] or a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician or a specialist paediatric gastroenterologist; OR

Must be treated by a paediatrician or a specialist paediatric gastroenterologist.

Note Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written applications for authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

infliximab 100 mg injection, 1 vial

5755X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	574.85	[a] Inflectra [HH]	[a] Remicade [JC]

▪ INFLIXIMAB

Note No applications for increased maximum quantities will be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Special Pricing Arrangements apply.

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CROHN DISEASE
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying drugs (bDMDs) for adult patients with severe Crohn disease. Where the term bDMDs appears in the following NOTES and restrictions, it refers to the tumour necrosis factor (TNF) alfa-antagonists (adalimumab and infliximab), the alpha-4 beta-7 integrin inhibitor (vedolizumab).
Patients are eligible for PBS-subsidised treatment with only 1 of the above PBS-subsidised biological disease modifying drugs at any one time.
From 1 August 2015, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised TNF-alfa antagonist or vedolizumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist or vedolizumab while they continue to show a response to therapy.
A patient who received PBS-subsidised TNF-alfa antagonist or vedolizumab treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist or vedolizumab more than twice.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist or vedolizumab treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist or vedolizumab under the new treatment cycle.
A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of bDMD therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised TNF-alfa antagonist or vedolizumab therapy after 1 August 2015.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised therapy with TNF-alfa antagonist or vedolizumab in this treatment cycle and wishes to commence such therapy (new patients); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy or vedolizumab and wishes to trial an alternate agent (recommencement) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist or vedolizumab following a break in PBS-subsidised therapy with that agent (change or re-commencement).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, 14 weeks of therapy for infliximab and 14 weeks of therapy for vedolizumab.
From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab or vedolizumab, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMD therapy.
For second and subsequent courses of PBS-subsidised TNF-alfa antagonist or vedolizumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Adalimumab only: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats and the second prescription should be written for 2 doses of 40 mg and 2 repeats for patients weighing 40 kg or greater. For patients weighing less than 40 kg, one prescription should be written for 2 doses of 40 mg with no repeats and the second prescription should be written for 2 doses of 20 mg with 3 repeats.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific TNF-alfa antagonist or vedolizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient

will be deemed to have failed to respond to treatment with that drug.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMD therapy is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist or vedolizumab within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy and immunosuppressive therapy.
A patient may trial the alternate bDMD therapy at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist or vedolizumab at the time of the application. However, they cannot swap to a particular bDMD therapy if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist or vedolizumab (where eligible in terms of disease severity) should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist or vedolizumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised bDMD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab.
A patient who commenced treatment with vedolizumab for severe Crohn disease prior to 1 August 2015 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for continuing treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Severe Crohn disease

Treatment Phase: Initial treatment (new patient - initial 1)

Clinical criteria:

Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, AND

Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; OR

Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to steroids, AND

Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR

Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug; OR

Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more months or have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contraindication to this drug, AND

Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 if affected by extensive small intestine disease; OR

Patient must have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 if not affected by extensive small intestine disease, short gut syndrome or is an ostomy patient, AND

Patient must have evidence of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR

Patient must have radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine; OR

Patient must (a) have evidence of intestinal inflammation, including: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; or (b) be assessed clinically as being in a high faecal output state; or (c) be assessed clinically

as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment; and

(v) the signed patient acknowledgement indicating they understand and acknowledge that the PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Authority required

Severe Crohn disease

Treatment Phase: Change or Re-commencement of treatment (initial 2)

Clinical criteria:

Patient must have a documented history of severe Crohn disease, AND

Patient must have received prior PBS-subsidised treatment with a biological disease modifying drug for this condition in this treatment cycle, AND

Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological disease modifying drug treatment including the details of date and duration of treatment.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological disease modifying drug (bDMD) therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised bDMD treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of bDMD treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of bDMD.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction.

Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

The assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

Note It is recommended that an application for continuing treatment is posted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Authority required

Severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment, AND

The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing treatment).

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

Authority required

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe Crohn disease, AND

Patient must have previously been issued with an authority prescription for this drug for this condition, AND

Patient must have demonstrated or sustained an adequate response to treatment with this drug, AND

Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR

Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

If the application is the first application for continuing treatment with this drug, an assessment of the patient's response to the initial course of treatment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

If fewer than the maximum stated repeats in the relevant treatment phase are requested at the time of the application, authority approvals for sufficient repeats to complete the balance of the stated repeats in the relevant treatment phase may be requested by telephone by contacting the Department of Human Services and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend the relevant treatment phase.

Up to a maximum of 2 repeats will be authorised.

infliximab 100 mg injection, 1 vial

5754W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	574.85	[a] Inflectra [HH]	[a] Remicade [JC]

▪ INFLIXIMAB

Note Special Pricing Arrangements apply.

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of infliximab and vedolizumab for adult patients with ulcerative colitis.

Patients are eligible for PBS-subsidised treatment with either infliximab or vedolizumab at any one time.

From 1 August 2015, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised infliximab or vedolizumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with infliximab or vedolizumab while they continue to show a response to therapy.

A patient who received PBS-subsidised infliximab or vedolizumab treatment prior to 1 August 2015 is considered to be in their first cycle as of 1 August 2015.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised infliximab or vedolizumab more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised infliximab or vedolizumab treatment in the most recent cycle to the date of the first application for initial treatment with infliximab or vedolizumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of either infliximab or vedolizumab in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of either infliximab or vedolizumab in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

(1) How to prescribe PBS-subsidised infliximab or vedolizumab therapy after 1 August 2015.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised treatment with infliximab or vedolizumab in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) infliximab or vedolizumab therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with infliximab or vedolizumab following a break in PBS-subsidised therapy with the same agent (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 14 weeks of therapy.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised treatment up to 12 weeks after the first dose (6 weeks following the third dose), and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.

For second and subsequent courses of PBS-subsidised infliximab or vedolizumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with infliximab or vedolizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted supply of treatment.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that drug.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised treatment is approved, a patient may swap if eligible to the alternate infliximab or vedolizumab treatment within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy.
A patient may trial the alternate treatment at any time, regardless of whether they are receiving therapy (initial or continuing) with infliximab or vedolizumab at the time of the application. However, they cannot swap to a particular therapy if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to the alternate infliximab or vedolizumab therapy should be accompanied by the approved authority prescription or remaining repeats for the therapy the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Mayo clinic score or partial Mayo clinic score submitted with the first authority application for infliximab or vedolizumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised infliximab or vedolizumab therapy of at least 5 years, must requalify for initial treatment with respect to the scores of disease severity. Patients must have received treatment with a 5-aminosalicylate oral preparation in a standard dose for induction of remission for a minimum of 3 consecutive months, and, either azathioprine, 6-mercaptopurine or tapered course of oral steroids (unless intolerance develops necessitating permanent treatment withdrawal) for a minimum of 3 consecutive months immediately prior to the time the Mayo score or PUCAI score is measured.
(5) Patients 'grandfathered' onto PBS-subsidised treatment with vedolizumab or infliximab.
A patient who commenced treatment with vedolizumab for moderate to severe ulcerative colitis prior to 1 August 2015 or infliximab prior to 1 December 2014 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.
A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment will be authorised under this criterion.
Following completion of the initial PBS-subsidised course, further applications for treatment will be assessed under the continuing treatment restriction of the relevant drug.
'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment (new patient - Initial 1)

Clinical criteria:

Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more months or have intolerance necessitating permanent treatment withdrawal, AND

Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR

Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months or have intolerance necessitating permanent treatment withdrawal; OR

Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, AND

Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR

Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR

Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years; OR

Patient must have previously received induction therapy with this drug for an acute severe episode of ulcerative colitis in the last 4 months and demonstrated an adequate response to induction therapy by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 (if aged 6 to 17 years).

Population criteria:

Patient must be 6 years of age or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician; OR

Must be treated by a specialist paediatric gastroenterologist.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 1 month old at the time of application.

Where treatment for an acute severe episode has occurred, an adequate response to induction therapy needs to be demonstrated by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 (if aged 6 to 17 years), within the first 12 weeks of receiving this drug for acute severe ulcerative colitis.

Patients who fail to achieve a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 within the first 12 weeks of receiving this drug for ulcerative colitis, or have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or have failed to maintain a PUCAI score less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose for patients administered doses at weeks 0, 2 and 6 (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The patient or guardian (required if patient is aged 6 to 17 years) must have signed a patient acknowledgement indicating that he or she understands and acknowledges that the PBS-subsidised treatment will cease if he or she does not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug for this condition, AND

Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR

Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician; OR

Must be treated by a specialist paediatric gastroenterologist.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Up to a maximum of 2 repeats will be authorised.

Note No applications for increased repeats will be authorised.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

HSD (Public)

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Initial PBS-subsidised treatment (Grandfather patient)

Clinical criteria:

Patient must have previously received non-PBS-subsidised therapy with this drug for this condition prior to 1 December 2014, AND

Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing treatment with this drug; OR

Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing treatment with this drug; OR

Patient must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 prior to commencing treatment with this drug; OR

Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced treatment with this drug where a Mayo clinic, partial Mayo clinic or PUCAI baseline assessment is not available, AND

Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR

Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.

Population criteria:

Patient must be 6 years of age or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician; OR

Must be treated by a specialist paediatric gastroenterologist.

Applications for authorisation of initial treatment must be in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and baseline Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) the date of commencement of this drug; and

(iii) the signed patient acknowledgement.

The current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment must be no more than 1 month old at the time of application. The baseline assessment must be from immediately prior to commencing treatment with this drug. Where a baseline assessment is not available the prescriber must contact the Department of Human Services to discuss.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Up to a maximum of 2 repeats will be authorised.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note The patient or guardian (required if patient is aged 6 to 17 years) must have signed a patient acknowledgement indicating that he or she understands and acknowledges that the PBS-subsidised treatment will cease if he or she does not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment.

Note No applications for increased repeats will be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Change or Re-commencement of treatment after a break in therapy (Initial 2)

Clinical criteria:

Patient must have previously been issued with an authority prescription for infliximab or vedolizumab for this condition in this treatment cycle, AND

Patient must not have failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician; OR

Must be treated by a specialist paediatric gastroenterologist.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of this drug within the timelines specified in the relevant restriction. If the response assessment to the previous course of this drug is not submitted as detailed in the relevant restriction, the patient will be deemed to have failed therapy with this drug.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Up to a maximum of 2 repeats will be authorised.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

Note No applications for increased repeats will be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete the 3 doses (i.e. the initial infusion regimen at 0, 2 and 6 weeks); OR

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; OR

Patient must have received insufficient therapy with this drug to complete 24 weeks of treatment under the Initial PBS-subsidised treatment restriction for patients who had previously received non-PBS subsidised treatment (Grandfathered patient), AND

The treatment must provide no more than the balance of up to 3 doses (new patients) or 2 repeats (Continuing or Grandfathered patients).

Population criteria:

Patient must be 6 years of age or older.

Treatment criteria:

Must be treated by a gastroenterologist (code 87); OR

Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR

Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR

Must be treated by a paediatrician; OR

Must be treated by a specialist paediatric gastroenterologist.

Written applications for authority approval for sufficient therapy to complete balance of supply should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority approval for sufficient therapy to complete a maximum of 3 initial doses or 2 repeats may be requested by telephone by contacting the Department of Human Services.

infliximab 100 mg injection, 1 vial

10196P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	574.85	[a] Inflectra [HH]	[a] Remicade [JC]

▪ INFLIXIMAB

Authority required

Active ankylosing spondylitis

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis, AND

Patient must not have received any PBS-subsidised treatment with either adalimumab, certolizumab pegol, etanercept, golimumab or infliximab in this treatment cycle, AND

Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender, AND

Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; AND

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The BASDAI must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application.

Both ESR and CRP measures should be provided with the initial treatment application and both must be no more than 1 month old. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form which must include the following:

(i) a copy of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a completed BASDAI Assessment Form; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) a signed patient acknowledgment.

The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

A maximum of 18 weeks of treatment with this drug will be approved under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) was approved in this cycle and the date of the first application under a new cycle.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Department of Human Services website at www.humanservices.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Department of Human Services website at www.humanservices.gov.au

Authority required

Ankylosing spondylitis

Treatment Phase: Initial 2 (change or recommencement for all patients)

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis, AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition in this treatment cycle, AND

Patient must not have failed PBS-subsidised therapy with this drug for this condition in the current treatment cycle, AND

Patient must be eligible to receive further bDMARD therapy.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

Where the most recent course of PBS-subsidised bDMARD treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy) the patient must have been assessed for response to that course following a minimum of 12 weeks of treatment. These assessments must be provided to the Department of Human Services no later than 4 weeks from the date the course was ceased. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

A maximum of 18 weeks of treatment with this drug will be approved under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.
Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.
From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.
A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent

(Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Authority required

Ankylosing spondylitis

Treatment Phase: Initial treatment – Initial 1 (new patients) or Initial 2 (change or recommencement for all patients) – balance of supply

Clinical criteria:

Patient must have active, or a documented history of active, ankylosing spondylitis, AND

Patient must have received insufficient therapy with this drug under the Initial 1 (new patients) restriction to complete 18 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement for all patients) restriction to complete 18 weeks treatment, AND

The treatment must provide no more than the balance of up to 18 weeks treatment available under the above restrictions.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

Note Authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 18 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826

GPO Box 9826
HOBART TAS 7001

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis, AND

Patient must have received this drug as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND

Patient must have demonstrated an adequate response to treatment with this drug.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

An adequate response is defined as an improvement from baseline of at least 2 of the BASDAI and 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ankylosing Spondylitis PBS Authority Application - Supporting Information Form.

All measurements provided must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

At the time of authority application, the doctor should request the appropriate number of vials, based on the weight of the patient, to provide for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

All applications for continuing treatment with this drug must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment following an initial treatment course it must be made following a minimum of 12 weeks of treatment with this drug. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under a new cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with active ankylosing spondylitis.
Where the term 'bDMARD' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 5 bDMARDs at any 1 time.
From 1 March 2007, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised bDMARDs without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.
A patient who received PBS-subsidised bDMARD treatment prior to 1 March 2007 is considered to be in their first cycle as of 1 March 2007.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once. A patient who, prior to 1 March 2007, was authorised to receive PBS-subsidised initial treatment for ankylosing spondylitis with the same agent twice, is exempt from this condition in respect of applications approved prior to 1 March 2007.
Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised bDMARD therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 bDMARDs in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI), or the prior NSAID therapy and exercise program requirements.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to these revised baseline measurements.
For a new patient, the BASDAI used to determine the baseline must be measured while the patient is receiving NSAID therapy and completing their exercise program.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.
(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 NSAID, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the BASDAI, ESR and/or CRP levels are measured.

Authority required

Ankylosing spondylitis

Treatment Phase: Continuing treatment – balance of supply

Clinical criteria:

Patient must have a documented history of active ankylosing spondylitis, AND

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

infliximab 100 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5753T	1	..	..	574.85	[a] Inflectra [HH]	[a] Remicade [JC]

▪ INFLIXIMAB

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis, AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND

Patient must have not failed previous PBS-subsidised treatment with infliximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

Patient must not receive more than 22 weeks of treatment under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application including severity.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised.

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD

treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before

swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND

Patient must not receive more than 22 weeks of treatment under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with infliximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

If a patient fails to demonstrate a response to a treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to

treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient infliximab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 22 weeks treatment; OR

Patient must have received insufficient infliximab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 22 weeks treatment, AND

The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to

Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have demonstrated an adequate response to treatment with infliximab, AND

Patient must have received infliximab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats will be authorised.

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

If a patient fails to demonstrate a response to treatment with infliximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the

C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Note Special Pricing Arrangements apply.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

Clinical criteria:

Patient must have received insufficient infliximab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

infliximab 100 mg injection, 1 vial

5757B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	574.85	[a] Inflectra [HH]	[a] Remicade [JC]

▪ INFLIXIMAB

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe active psoriatic arthritis, AND

Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, AND

Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, AND

Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR

Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, AND

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or ustekinumab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis, AND

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, AND

Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, AND

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or ustekinumab.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab for adult patients with severe active psoriatic arthritis.
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.
Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab only.
Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.
Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.
Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an

alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.
Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.
Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
Grandfather patients - ustekinumab only.
For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 22 weeks treatment, AND

The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis, AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND

Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab, infliximab or ustekinumab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab for adult patients with severe active psoriatic arthritis.
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.
Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab, infliximab and ustekinumab only.
Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.
Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].
The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.
Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.
Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe active psoriatic arthritis.
(1) Initial treatment.
Applications for initial treatment should be made where:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab, and 28 weeks of therapy for ustekinumab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.
Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
Grandfather patients - ustekinumab only.
For patients who commenced treatment with ustekinumab for psoriatic arthritis prior to 1 May 2016, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Continuing treatment.
Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.
(3) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.
Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or

continuing) with a biological agent at the time of the application or not.
Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:
(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.
(4) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.
(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

infliximab 100 mg injection, 1 vial

5756Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	574.85	[a] Inflectra [HH]	[a] Remicade [JC]

▪ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, secukinumab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, secukinumab and ustekinumab only.
Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.
Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.
Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.
Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.
Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.
Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.
There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.
How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Application for approval for initial treatment.
Applications for a course of initial treatment should be made in the following situations:
(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
(iii) patients who wish to recommence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).
All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab, etanercept and secukinumab, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.
Grandfather patients (secukinumab only).
Applications for patients who commenced treatment with secukinumab for chronic plaque psoriasis prior to 1 September 2015 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.
Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Application for continuing treatment.
Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.
For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
(4) Swapping therapy.
Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.
To ensure patients receive the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.
(5) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6

weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

Note No increase in the maximum number of repeats may be authorised.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, AND

Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, AND

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, AND

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, AND

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, AND

Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, AND

Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, AND

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, AND

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, AND

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, AND

Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment) restriction to complete 22 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment) restriction to complete 22 weeks treatment, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND

Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to

the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, AND

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, AND

Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, AND

The treatment must be as systemic monotherapy (other than methotrexate), AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, AND

The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

infliximab 100 mg injection, 1 vial

5758C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	574.85	[a] Inflectra [HH]	[a] Remicade [JC]

Interleukin inhibitors

▪ ANAKINRA

Note This drug is not PBS-subsidised for conditions other than CAPS.

Authority required (STREAMLINED)

5450

Moderate to severe cryopyrin associated periodic syndromes (CAPS)

Treatment criteria:

Must be treated by a rheumatologist or in consultation with a rheumatologist; OR

Must be treated by a rheumatologist or in consultation with a rheumatologist; OR

Must be treated by a clinical immunologist or in consultation with a clinical immunologist; OR

Must be treated by a clinical immunologist or in consultation with a clinical immunologist.

A diagnosis of CAPS must be documented in the patient's medical records.

anakinra 100 mg/0.67 mL injection, 28 x 0.67 mL syringes

10264F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	1650.00	Kineret [FK]

▪ TOCILIZUMAB

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

Clinical criteria:

Patient must have severe active juvenile idiopathic arthritis, AND

Patient must have received no prior PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition; OR

Patient must not have received PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in the previous 12 months, AND

Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR

Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; or (ii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age and a parent or authorised guardian must have signed a patient acknowledgement.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) an acknowledgement signed by a parent or authorised guardian.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised bDMARD was stopped and the date of the first application under a new treatment cycle.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 12 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis, AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, AND

Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (change or recommencement of treatment after break of less than 12 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 12 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a paediatric rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis, AND

Patient must have demonstrated an adequate response to treatment with tocilizumab, AND

Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient who has severe active juvenile idiopathic arthritis. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to

have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised biological therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 12 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 12 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 12 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 12 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with bDMARDs should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment – balance of supply

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

tocilizumab 200 mg/10 mL injection, 10 mL vial

10056G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	336.90	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

10064Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	670.29	Actemra [RO]

tocilizumab 80 mg/4 mL injection, 4 mL vial

10077J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	135.95	Actemra [RO]

▪ TOCILIZUMAB

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months; OR

Patient must have received no PBS-subsidised bDMARD treatment for at least 5 years if they failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) in their last treatment cycle, AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle. A patient may re-trial tocilizumab after a minimum of 5 years have elapsed between the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle and the date of the first application under a new treatment cycle.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.

A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after break of less than 24 months)

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND

Patient must have received prior PBS-subsidised treatment with adalimumab, etanercept or tocilizumab for this condition in this treatment cycle, AND

Patient must not have failed PBS-subsidised therapy with tocilizumab for this condition in the current treatment cycle, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.
Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.

(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, AND

Patient must have demonstrated an adequate response to treatment with tocilizumab, AND

Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment in this treatment cycle, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'biological disease modifying anti-rheumatic drug' and 'bDMARD' mean adalimumab, etanercept or tocilizumab.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to respond to PBS-subsidised bDMARD treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised bDMARD therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term bDMARD appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the 3 bDMARDs at any one time.
From 1 April 2014, a patient receiving PBS-subsidised bDMARD therapy is considered to be in a treatment cycle where they may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:
(i) continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy; and
(ii) fail to respond or to sustain a response to each PBS-subsidised bDMARD once only.

Once a patient has either failed or ceased to respond to PBS-subsidised bDMARD treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised bDMARD therapy before they are eligible to receive further PBS-subsidised bDMARD therapy. The length of a treatment break is measured from the date of the last approval for PBS-subsidised bDMARD therapy in the last treatment cycle to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
A patient who was receiving PBS-subsidised bDMARD treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in bDMARD treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle.
A patient who has failed fewer than 3 trials of a bDMARD in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment was stopped to the date of the first application for initial treatment with a bDMARD under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 April 2014.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.
A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.
A patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the current treatment cycle.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count submitted with the first authority application for a bDMARD. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the Department of Human Services will assess response according to the revised baseline measurement.
(4) Re-commencement of treatment after a 24 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised bDMARD therapy of at least 24 months, must requalify for treatment under the Initial 1 treatment restriction.

Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment – balance of supply

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

tocilizumab 200 mg/10 mL injection, 10 mL vial

10058J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	336.90	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

10072D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	670.29	Actemra [RO]

tocilizumab 80 mg/4 mL injection, 4 mL vial

10081N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	135.95	Actemra [RO]

▪ TOCILIZUMAB

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis, AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND

Patient must not have failed previous PBS-subsidised treatment with tocilizumab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a

further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.

Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) completed authority prescription form(s); and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to a treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 24 months) or Initial 2 (change or recommencement of treatment after break of less than 24 months) – balance of supply.

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Initial 1 (new patient or patient recommencing treatment after break of more than 24 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient tocilizumab therapy under the Initial 2 (change or recommencement of treatment after break of less than 24 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have demonstrated an adequate response to treatment with tocilizumab, AND

Patient must have received tocilizumab as their most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

If a patient fails to demonstrate a response to treatment with tocilizumab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated

kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.
For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.
A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.
The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.
(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.
(a) Initial treatment.
Applications for initial treatment should be made where:
(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or
(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or
(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or
(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).
Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.
Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.
A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.
Abatacept patients:
Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.
Rituximab patients:
A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.
(b) Continuing treatment.
Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.
It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.
Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.
Rituximab patients:
A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.
Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.
(2) Swapping therapy.
Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD

without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.
Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.
A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements. To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing Treatment – balance of supply.

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

tocilizumab 200 mg/10 mL injection, 10 mL vial

9658H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	336.90	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

9659J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	670.29	Actemra [RO]

tocilizumab 80 mg/4 mL injection, 4 mL vial

9657G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	135.95	Actemra [RO]

▪ TOCILIZUMAB

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of tocilizumab for a patient who has severe active systemic juvenile idiopathic arthritis (sJIA).

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show a response to therapy, and

(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

Once a patient has either failed or ceased to respond to 2 courses of treatment, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 12 month break in PBS-subsidised tocilizumab therapy before they are eligible to receive further PBS-subsidised tocilizumab therapy. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was stopped to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

A patient who was receiving PBS-subsidised tocilizumab treatment immediately prior to 1 May 2012 is considered to be in their first cycle as of 1 May 2012. A patient who has had a break in tocilizumab treatment of at least 12 months immediately prior to making a new application, on or after 1 May 2012, will commence a new treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of less than 12 months may commence a second course of treatment within the same treatment cycle.

A patient who has failed their first course of tocilizumab in a treatment cycle and who has a break in therapy of more than 12 months must commence a new treatment cycle.

(1) How to prescribe PBS-subsidised tocilizumab therapy after 1 May 2012.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised tocilizumab treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or

(ii) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of more than 12 months (Initial 1); or

(iii) a patient has received the first course of PBS-subsidised (initial or continuing) tocilizumab therapy in a treatment cycle and is deemed to have failed to respond or sustain a response and the treating physician wishes to trial a second course, provided any break in therapy is less than 12 months (Initial 2); or

(iv) a patient wishes to recommence treatment with tocilizumab following a break in PBS-subsidised therapy of less than 12 months (Initial 2).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy, and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab for that course.

For second and subsequent courses of PBS-subsidised tocilizumab, it is recommended that a patient is reviewed in the 4 weeks prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

(b) Continuing treatment.

Following the completion of an initial treatment course with tocilizumab, a patient may qualify to receive up to 24 weeks of continuing treatment with tocilizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted tocilizumab supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

(2) Treatment cycle.

Once initial treatment with PBS-subsidised tocilizumab is approved, a patient deemed to have failed to respond to the first course of treatment may have a second course without having to requalify with respect to the indices of disease severity (joint count, fever and/or CRP level and platelet count) or the prior therapy requirements, except if the patient has had a break in therapy of more than 12 months.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(3) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the relevant baseline measurements of the joint count, fever and/or CRP level and platelet count submitted with the first authority application for tocilizumab.

Where a patient is deemed to have failed to respond or to sustain a response to the first course of therapy in a treatment cycle, prescribers may provide new baseline measurements for the second course of treatment within that cycle. The Department of Human Services will assess response according to these revised baseline measurements. If new baseline measurements are not submitted with the initial application for the second course of treatment, then those submitted with

the first course will be used by the Department of Human Services to assess response to the second course.
(4) Recommencement of treatment after a 12 month break in PBS-subsidised therapy.
A patient who wishes to start a second or subsequent treatment cycle following a break in PBS-subsidised tocilizumab therapy of at least 12 months, must requalify for treatment under the Initial 1 treatment restriction.
(5) Withdrawal of treatment after sustained remission.
Withdrawal of treatment with tocilizumab should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be submitted to the Department of Human Services at the time treatment is ceased.

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months)

Clinical criteria:

Patient must have been diagnosed with systemic juvenile idiopathic arthritis, AND

Patient must have received no prior PBS-subsidised treatment with tocilizumab for this condition; OR

Patient must not have received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months, AND

Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR

Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR

Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR

Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR

Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy; OR

Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

Patient must be under 18 years of age.

Treatment criteria:

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 2 active joints; and

(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or

(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes the following:

(i) the date of assessment of severe active systemic juvenile idiopathic arthritis;

(ii) details of prior treatment including dose and duration of treatment;

(iii) pathology reports detailing CRP and platelet count where appropriate; and

(3) an acknowledgement signed by a parent or authorised guardian.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

If a patient fails to respond to 2 courses of treatment in a treatment cycle they will not be eligible to receive further PBS-subsidised tocilizumab therapy in that treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

Note To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be provided for all subsequent continuing treatment applications.

Note Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)

Clinical criteria:

Patient must have a documented history of systemic juvenile idiopathic arthritis, AND

Patient must have received PBS-subsidised treatment with tocilizumab for this condition in the previous 12 months, AND

Patient must not have failed to demonstrate an adequate response to PBS-subsidised therapy with tocilizumab for this condition more than once in the current treatment cycle, AND

Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes pathology reports detailing C-reactive protein (CRP) level and platelet count where appropriate.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Applications for a patient who has received PBS-subsidised treatment with tocilizumab in this treatment cycle and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised tocilizumab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under either of the Initial 1 or 2 treatment restrictions, the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised tocilizumab treatment was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment must be submitted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to that course of treatment with tocilizumab.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

Note Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 4 weeks from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with tocilizumab.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy under the Initial 1 (new patient or patient recommencing treatment after a break of more than 12 months) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy under the Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment, AND

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of systemic juvenile idiopathic arthritis, AND

Patient must have demonstrated an adequate response to their most recent course of PBS-subsidised treatment with tocilizumab, AND

Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity submitted with the initial treatment application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Systemic Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form which includes baseline and current pathology reports detailing CRP and platelet count where appropriate.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 1 month old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one months supply). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

All applications for continuing treatment with tocilizumab must include a measurement of response to the most recent prior course of therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with tocilizumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with tocilizumab.

Patients are eligible to receive continuing tocilizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

If a patient fails to respond to 2 courses of treatment they will not be eligible to receive further PBS-subsidised tocilizumab therapy in this treatment cycle. A patient may retrial tocilizumab after a minimum of 12 months have elapsed between the date the last PBS-subsidised treatment was stopped and the date of the first application under a new treatment cycle.

Note An assessment of the patient's response to a continuing course of therapy should be made within the 4 weeks prior to completion of that course and posted to the Department of Human Services no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criteria.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

Patient must have received insufficient tocilizumab therapy under the Continuing Treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a rheumatologist; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre; OR

Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

tocilizumab 200 mg/10 mL injection, 10 mL vial

1481Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	336.90	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

1482B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	670.29	Actemra [RO]

tocilizumab 80 mg/4 mL injection, 4 mL vial

1476Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	135.95	Actemra [RO]

Calcineurin inhibitors

▪ CYCLOSPORIN

Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

3333

For use by organ or tissue transplant recipients

cyclosporin 50 mg/mL injection, 10 x 1 mL ampoules

5631J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	54.10	Sandimmun [NV]

▪ CYCLOSPORIN

Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

3328

Management of rejection in patients following organ or tissue transplantation, under the supervision and direction of a transplant unit. Management includes initiation, stabilisation and review of therapy as required

Authority required (STREAMLINED)

3329

Management (which includes initiation, stabilisation and review of therapy) by dermatologists or clinical immunologists of patients with severe atopic dermatitis for whom other systemic therapies are ineffective or inappropriate

Authority required (STREAMLINED)

3330

Management (which includes initiation, stabilisation and review of therapy) by dermatologists of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life

Authority required (STREAMLINED)

3331

Management (which includes initiation, stabilisation and review of therapy) by nephrologists of patients with nephrotic syndrome in patients in whom steroids and cytostatic drugs have failed or are not tolerated or are considered inappropriate and in whom renal function is unimpaired

Authority required (STREAMLINED)

3332

Management (which includes initiation, stabilisation and review of therapy) by rheumatologists or clinical immunologists of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate

cyclosporin 10 mg capsule, 60

5632K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	..	*74.40	Neoral 10 [NV]

cyclosporin 100 mg capsule, 30

5636P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	5	..	*651.08	[a] Cyclosporin Sandoz [SZ]	[a] Neoral 100 [NV]

cyclosporin 100 mg/mL oral liquid, 50 mL

5633L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	5	..	*1263.16	Neoral [NV]

cyclosporin 25 mg capsule, 30

5634M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	5	..	*153.56	[a] Cyclosporin Sandoz [SZ]	[a] Neoral 25 [NV]

cyclosporin 50 mg capsule, 30

5635N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	5	..	*319.52	[a] Cyclosporin Sandoz [SZ]	[a] Neoral 50 [NV]

▪ TACROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

5569

Management of rejection in patients following organ or tissue transplantation

Clinical criteria:

The treatment must be under the supervision and direction of a transplant unit, AND

The treatment must include initiation, stabilisation, and review of therapy as required.

tacrolimus 1 mg capsule, 100

9560E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*500.28	[a] Pharmacor Tacrolimus 1 [CR] [a] TACROLIMUS APOTEX [TX]	[a] Prograf [LL] [a] Tacrolimus Sandoz [SZ]

tacrolimus 1 mg capsule: modified release, 60

9665Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*300.16	Prograf XL [LL]

tacrolimus 5 mg capsule, 50

9561F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1250.08	[a] Pharmacor Tacrolimus 5 [CR] [a] TACROLIMUS APOTEX [TX]	[a] Prograf [LL] [a] Tacrolimus Sandoz [SZ]

tacrolimus 5 mg capsule: modified release, 30

9666R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*750.44	Prograf XL [LL]

tacrolimus 500 microgram capsule, 100

9558C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*250.14	[a] Pharmacor Tacrolimus 0.5 [CR] [a] TACROLIMUS APOTEX [TX]	[a] Prograf [LL] [a] Tacrolimus Sandoz [SZ]

tacrolimus 500 microgram capsule: modified release, 30

9664P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*75.04	Prograf XL [LL]

Other immunosuppressants

▪ LENALIDOMIDE

Note Special Pricing Arrangements apply.

Authority required

Myelodysplastic syndrome

Treatment Phase: Initial treatment

Clinical criteria:

The treatment must be limited to a maximum duration of 16 weeks, AND

Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), AND

Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, AND

Patient must be red blood cell transfusion dependent.

Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination: less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias.

Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations:

1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR
2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR
5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias.

Classification of a patient as red blood cell transfusion dependent requires that:

(i) the patient has been transfused within the last 8 weeks; and

(ii) the patient has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and would be expected to continue this requirement without lenalidomide treatment.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Myelodysplastic Syndrome Lenalidomide Authority Application - Supporting Information Form; and

(c) a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and

(d) a copy of the full blood examination report; and

(e) a copy of the pathology report detailing the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note: using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS -5q is acceptable); and

(f) details of transfusion requirements including: (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red cell units transfused in the 4 and 6 months preceding the date of this application; and

(g) a signed patient acknowledgement form.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), AND

Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, AND

Patient must have received PBS-subsidised initial therapy with lenalidomide for myelodysplastic syndrome, AND

Patient must have achieved and maintained transfusion independence; or least a 50% reduction in red blood cell unit transfusion requirements compared with the four month period prior to commencing initial PBS-subsidised therapy with lenalidomide, AND

Patient must not have progressive disease.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

The first authority application for continuing supply must be made in writing. Subsequent authority applications for continuing supply may be made by telephone.

The following evidence of response must be provided at each application:

(i) a haemoglobin level taken within the last 4 weeks; and

(ii) the date of the last transfusion; and

(iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application; and

(iv) a statement confirming that the patient has not progressed to acute myeloid leukaemia.

Note Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Subsequent authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

lenalidomide 10 mg capsule, 21

2802L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	3	..	5361.16	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

2799H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	3	..	5122.76	Revlimid [CJ]

▪ LENALIDOMIDE

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

Clinical criteria:

The condition must be confirmed by a histological diagnosis, AND

The treatment must be as monotherapy; OR

The treatment must be in combination with dexamethasone, AND

Patient must have progressive disease after at least one prior therapy, AND

Patient must have undergone or be ineligible for a primary stem cell transplant, AND

Patient must have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease, AND

Patient must not be receiving concomitant PBS-subsidised bortezomib.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Thalidomide treatment failure is defined as:

(1) confirmed disease progression during thalidomide treatment or within 6 months of discontinuing thalidomide treatment; or

(2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment.

Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living.

Toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity.

Failure to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease is defined as:

(1) less than a 25% reduction in serum or urine M protein; or

(2) in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum free light chain levels.

If the dosing requirement for thalidomide cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and

(3) duration of thalidomide and daily dose prescribed; and

(4) a signed patient acknowledgment.

To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

Clinical criteria:

Patient must have previously received an authority prescription for lenalidomide, AND

Patient must not have progressive disease, AND

The treatment must be as monotherapy; OR

The treatment must be in combination with dexamethasone.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

lenalidomide 10 mg capsule, 21

5784K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	5361.16	Revlimid [CJ]

lenalidomide 15 mg capsule, 21

5785L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	6252.53	Revlimid [CJ]

lenalidomide 25 mg capsule, 21

5786M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	6587.49	Revlimid [CJ]

lenalidomide 5 mg capsule, 21

5783J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	..	..	5122.76	Revlimid [CJ]

▪ POMALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment

Clinical criteria:

The treatment must be in combination with dexamethasone, AND

Patient must have undergone or be ineligible for a primary stem cell transplant, AND

Patient must have experienced treatment failure with lenalidomide, AND

Patient must have experienced treatment failure with bortezomib, AND

Patient must not be receiving concomitant PBS-subsidised thalidomide, lenalidomide or bortezomib.

Bortezomib treatment failure is the absence of achieving at least a partial response or as progressive disease during treatment or within 6 months of discontinuing treatment with bortezomib. Lenalidomide treatment failure is progressive disease during treatment or within 6 months of discontinuing treatment with lenalidomide.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma pomalidomide Authority Application Supporting Information form; and

(3) reports demonstrating the patient has failed treatment with lenalidomide and bortezomib.

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug, AND

Patient must not have progressive disease, AND

The treatment must be in combination with dexamethasone, AND

Patient must not be receiving concomitant PBS-subsidised thalidomide, lenalidomide or bortezomib.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Written applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

pomalidomide 3 mg capsule, 21

10406Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	10500.00	Pomalyst [CJ]

pomalidomide 4 mg capsule, 21

10387Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	10500.00	Pomalyst [CJ]

▪ RITUXIMAB

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS
The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying antirheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus-associated kinase (JAK) inhibitor (tofacitinib).
Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.
In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.
A patient receiving PBS-subsidised bDMARD therapy may swap to an alternate bDMARD without having to experience a disease flare. Under these interchangeability arrangements:
- a patient may continue to receive long-term treatment with a PBS-subsidised bDMARD while they continue to show a

response to therapy,
- a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once, and
- once a patient has either failed or ceased to respond to treatment 5 times, they will not be eligible to receive further PBS-subsidised bDMARDs for the treatment of rheumatoid arthritis.

For patients who have failed PBS-subsidised treatment with 2 or 3 TNF-alfa antagonists prior to 1 August 2010 please contact the Department of Human Services on 1800 700 270.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has a break in therapy of less than 24 months may commence a further course of treatment with a bDMARD without having to requalify under the Initial 1 treatment restriction. A patient who has failed fewer than 5 bDMARDs and who has had a break in therapy of longer than 24 months must requalify for treatment under the Initial 1 treatment restriction.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised bDMARD treatment is stopped to the date of the new application for treatment with a bDMARD.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2010.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient wishes to re-commence treatment with a bDMARD following a break in PBS-subsidised therapy of more than 24 months (Initial 1); or

(iii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iv) a patient wishes to re-commence treatment with a specific bDMARD following a break of less than 24 months in PBS-subsidised therapy with that agent (Initial 2).

Initial applications for new or re-commencing patients (Initial 1) must include a joint count and ESR and/or CRP measured at the completion of the 6-month intensive DMARD trial, but prior to ceasing DMARD therapy.

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for abatacept, adalimumab, etanercept, golimumab, tocilizumab and tofacitinib, 18 to 20 weeks of therapy with certolizumab pegol (depending upon the dosing regimen), 22 weeks of therapy for infliximab and 2 infusions of rituximab.

A patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to the Department of Human Services within 4 weeks.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) treatment it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Abatacept patients:

Patients are eligible to receive one I.V. loading dose when commencing treatment with the subcutaneous formulation. For these patients two prescriptions are required, the first prescription for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription for the pre-filled syringes, with a maximum quantity of 4 and up to 3 repeats, must be submitted with the initial application.

Rituximab patients:

A further application may be submitted to the Department of Human Services 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements, except if the patient has had a break in therapy of more than 24 months. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to

respond to prior treatment with that drug.
Abatacept patients:
Patients swapping from I.V. abatacept to subcutaneous abatacept will not be eligible for an I.V. loading dose when commencing treatment with the subcutaneous formulation.
In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.
To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.
PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.
To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.
(3) Baseline measurements to determine response.
the Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints.
Except as specified under the Initial 1 treatment restriction, a baseline joint count and ESR and/or CRP should be performed whilst the patient is still on treatment or within 1 month of ceasing prior treatment. Applications under the Initial 1 treatment restriction for new or re-commencing patients must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (patient recommencing treatment after a break of more than 24 months)

Clinical criteria:

Patient must have severe active rheumatoid arthritis, AND

Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist, AND

Patient must have received no PBS-subsidised treatment with a biological disease modifying anti-rheumatic drug (bDMARD) for this condition in the previous 24 months, AND

Patient must not have failed previous PBS-subsidised treatment with rituximab for this condition, and have not already failed, or ceased to respond to, PBS-subsidised bDMARD treatment for this condition 5 times, AND

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if 3 or more of methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above, must include at least 3 months continuous treatment with each of at least 2 DMARDs, with one or more of the following DMARDs being used in place of the DMARDS which are contraindicated or not tolerated: (i) azathioprine at a dose of at least 1 mg/kg per day; and/or (ii) cyclosporin at a dose of at least 2 mg/kg/day; and/or (iii) sodium aurothiomalate at a dose of 50 mg weekly, AND

Patient must not receive more than 2 infusions of rituximab under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'TNF' alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose,the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form; and

(3) a signed patient acknowledgement.

Assessment of a patient's response to an initial course of treatment must be made at least 12 weeks after the first infusion so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services within 4 weeks of the date it was conducted. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient who fails to demonstrate a response to treatment with rituximab under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who fails to demonstrate a response to rituximab treatment and who qualifies to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP is provided with the initial application, the same marker will be used to determine response

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:
(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or re-commencement of treatment after break of less than 24 months).

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have failed to respond to at least 1 PBS-subsidised tumour necrosis factor (TNF) alfa antagonist, AND

Patient must have received prior PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition and are eligible to receive further bDMARD therapy, AND

Patient must not receive more than 2 infusions of rituximab under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction 'TNF' alfa antagonist means adalimumab, certolizumab pegol, etanercept, golimumab and infliximab.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) completed authority prescription form(s); and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

Applications for a patient who has received PBS-subsidised treatment with rituximab and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised rituximab treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised rituximab treatment was approved under either of the initial 1 or 2 treatment restrictions, the patient must have been assessed for response at least 12 weeks after the first infusion. This assessment must be submitted no later than 4 weeks from the date of the assessment.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If a patient fails to demonstrate a response to a treatment with rituximab and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Authority required

Severe active rheumatoid arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active rheumatoid arthritis, AND

Patient must have demonstrated an adequate response to treatment with this drug, AND

Patient must have received this drug as the most recent course of PBS-subsidised biological disease modifying anti-rheumatic drug (bDMARD) treatment for this condition, AND

Patient must not receive more than 2 infusions of rituximab under this restriction, AND

The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a rheumatologist; OR

Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

For the purposes of this restriction bDMARD means abatacept, adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, tocilizumab or tofacitinib.

The authority application must be made in writing and must include:

(a) completed authority prescription form(s); and

(b) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form.

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent provided they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The demonstration of response must be submitted within 4 weeks of assessment.

Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with rituximab.

A patient whose most recent course of PBS-subsidised therapy was with rituximab and whose response to this treatment is sustained for more than 12 months, may apply for a further course of rituximab under the Continuing treatment restriction.

If a patient fails to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

rituximab 500 mg/50 mL injection, 50 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9544H	1	..	..	1898.92	Mabthera [RO]

▪ THALIDOMIDE

Caution Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program.

Authority required (STREAMLINED)
5914
Multiple myeloma

thalidomide 100 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9667T	2	..	..	*1596.00	Thalomid [CJ]

thalidomide 50 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9566L	4	..	..	*1596.00	Thalomid [CJ]

▪ MUSCULO-SKELETAL SYSTEM

▪ MUSCLE RELAXANTS

MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

Other centrally acting agents

▪ BACLOFEN

Authority required (STREAMLINED)
6000
Severe chronic spasticity
Clinical criteria:
Patient must have failed to respond to treatment with oral antispastic agents; OR
Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND
Patient must have chronic spasticity of cerebral origin.
Authority required (STREAMLINED)
6003
Severe chronic spasticity
Clinical criteria:
Patient must have failed to respond to treatment with oral antispastic agents; OR
Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND
Patient must have chronic spasticity due to multiple sclerosis.
Authority required (STREAMLINED)
5990
Severe chronic spasticity
Clinical criteria:
Patient must have failed to respond to treatment with oral antispastic agents; OR
Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND
Patient must have chronic spasticity due to spinal cord injury.
Authority required (STREAMLINED)
6051
Severe chronic spasticity
Clinical criteria:
Patient must have failed to respond to treatment with oral antispastic agents; OR
Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND
Patient must have chronic spasticity due to spinal cord disease.

baclofen 10 mg/5 mL injection: intrathecal, 5 mL ampoule

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5617P	10	..	..	*1246.30	[a] Bacthecal [DZ]	[a] Lioresal Intrathecal [NV]

DRUGS FOR TREATMENT OF BONE DISEASES

DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

Bisphosphonates

IBANDRONATE

Authority required (STREAMLINED)

5291

Bone metastases

Clinical criteria:

The condition must be due to breast cancer.

ibandronate 6 mg/6 mL injection, 6 mL vial

5750P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	11	..	324.29	Bondronat [RO]

PAMIDRONATE DISODIUM

Authority required (STREAMLINED)

4433

Hypercalcaemia of malignancy

Clinical criteria:

Patient must have a malignancy refractory to anti-neoplastic therapy.

pamidronate disodium 15 mg/5 mL injection, 5 mL vial

5667G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	4	2	..	*55.24	Pamisol [HH]

pamidronate disodium 30 mg/10 mL injection, 10 mL vial

5668H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	2	..	*55.26	Pamisol [HH]

pamidronate disodium 60 mg/10 mL injection, 10 mL vial

5669J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	2	..	55.26	Pamisol [HH]

PAMIDRONATE DISODIUM

Authority required (STREAMLINED)

4433

Hypercalcaemia of malignancy

Clinical criteria:

Patient must have a malignancy refractory to anti-neoplastic therapy.

Authority required (STREAMLINED)

5218

Multiple myeloma

Authority required (STREAMLINED)

5291

Bone metastases

Clinical criteria:

The condition must be due to breast cancer.

pamidronate disodium 90 mg/10 mL injection, 10 mL vial

5670K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	11	..	82.89	Pamisol [HH]

ZOLEDRONIC ACID

Note Pharmaceutical benefits that have the form zoledronic acid 4 mg/100 mL injection and pharmaceutical benefits that have the form zoledronic acid 4 mg/5 mL injection are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

5735

Multiple myeloma

Authority required (STREAMLINED)

5605

Bone metastases

Clinical criteria:

The condition must be due to breast cancer.

Authority required (STREAMLINED)

5703
Bone metastases
Clinical criteria:
The condition must be due to castration-resistant prostate cancer.
Authority required (STREAMLINED)
5704
Hypercalcaemia of malignancy
Clinical criteria:
Patient must have a malignancy refractory to anti-neoplastic therapy.

zoledronic acid 4 mg/100 mL injection, 100 mL bag

10561W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	11	..	326.97	[a] DBL Zoledronic Acid [HH]

zoledronic acid 4 mg/100 mL injection, 100 mL vial

10548E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	11	..	326.97	[a] Zometa [NV]

zoledronic acid 4 mg/5 mL injection, 5 mL vial

9653C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	326.97	[a] APO-Zoledronic Acid [TX] [a] Zometa [NV]	[a] DBL Zoledronic Acid [HH]

HSD (Public)

NERVOUS SYSTEM

ANTI-PARKINSON DRUGS

DOPAMINERGIC AGENTS

Dopa and dopa derivatives

LEVODOPA + CARBIDOPA ANHYDROUS

Note Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.
Note A positive clinical response to Duodopa administered via a temporary nasoduodenal tube should be confirmed before a permanent percutaneous endoscopic gastrostomy (PEG) tube is inserted.

Authority required (STREAMLINED)
6179
Advanced Parkinson disease
Clinical criteria:
Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, AND
The treatment must be commenced in a hospital-based movement disorder clinic.

levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL

9743T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	8	5	..	*11536.00	Duodopa [VE]

Dopamine agonists

APOMORPHINE

Authority required (STREAMLINED)
4833
Parkinson disease
Clinical criteria:
Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy.

apomorphine hydrochloride 10 mg/mL injection, 5 x 1 mL ampoules

10227G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	72	5	..	*3021.12	Apomine [HH]

apomorphine hydrochloride 20 mg/2 mL injection, 5 x 2 mL ampoules

5609F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	72	5	..	*6045.12	Movapo [TD]

apomorphine hydrochloride 50 mg/5 mL injection, 5 x 5 mL ampoules

5610G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	36	5	..	*7562.88	Movapo [TD]

PSYCHOLEPTICS

ANTIPSYCHOTICS

Diazepines, oxazepines, thiazepines and oxepines

CLOZAPINE

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Novartis Clozaril Patient Monitoring System (eCPMS) or Hospira Clopineconnect.

Authority required (STREAMLINED)

5015

Schizophrenia

Treatment Phase: Initial treatment

Clinical criteria:

Patient must be non-responsive to other neuroleptic agents; OR

Patient must be intolerant of other neuroleptic agents.

Treatment criteria:

Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient.

Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.

The name of the consulting psychiatrist should be included in the patient's medical records.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

clozapine 100 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5629G	2	..	..	*242.38	[a] Clopine 100 [HH]	[a] Clozaril 100 [NV]

clozapine 200 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
5627E	2	..	..	*484.76	Clopine 200 [HH]

clozapine 25 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5628F	2	..	..	*64.64	[a] Clopine 25 [HH]	[a] Clozaril 25 [NV]

clozapine 50 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
5626D	2	..	..	*129.28	Clopine 50 [HH]

clozapine 50 mg/mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
5630H	1	..	..	135.00	Clopine Suspension [HH]

RESPIRATORY SYSTEM

DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

Other systemic drugs for obstructive airway diseases

OMALIZUMAB

Note Special Pricing Arrangements apply.

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment

Clinical criteria:

Patient must be under the care of the same physician for at least 12 months, AND

Patient must have a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days, AND

Patient must have a duration of asthma of at least 1 year, AND

Patient must have forced expiratory volume (FEV1) less than or equal to 80% predicted, documented on 3 or more occasions in the previous 12 months, AND

Patient must have past or current evidence of atopy, documented by skin prick testing or RAST, AND

Patient must have total serum human immunoglobulin E greater than or equal to 30 IU/mL, AND

Patient must have signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment, AND

Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, AND

Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 12 years or older.

Treatment criteria:

Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Optimised asthma therapy includes:

(i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or eformoterol 12 micrograms bd) for at least 12 months, unless contraindicated or not tolerated, AND

(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.

The initial IgE assessment must be no more than 12 months old at the time of application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 22 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form,

which includes the following:

(i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(ii) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(iii) the signed patient acknowledgement; and

(c) the IgE pathology report; and

(d) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note It is recommended that an application for continuing treatment is submitted at the time of the 22 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA
Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.
Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised omalizumab therapy:
(a) Initial treatment:
Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.
(b) Continuing treatment:
Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.
(2) Baseline measurements to determine response:
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.
(4) Monitoring of patients:
Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment, AND

The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Note Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe allergic asthma, AND

Patient must have demonstrated or sustained an adequate response to treatment with this drug, AND

Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 18 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form which includes details of maintenance oral corticosteroid dose; and

(c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms.

Note If the same physician cannot assess the patient please call the Department of Human Services on 1800 700 270.

Note For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note It is recommended that an application for continuing treatment is submitted at the time of the 18 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA
Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.
Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
(1) How to prescribe PBS-subsidised omalizumab therapy:
(a) Initial treatment:
Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.
(b) Continuing treatment:
Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.
(2) Baseline measurements to determine response:
The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and the Department of Human Services will assess response according to these revised baseline measurements.
(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:
Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Authority required

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, AND

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

omalizumab 150 mg/mL injection, 1 mL syringe

10109C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	410.00	Xolair [NV]

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

10118M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	..	..	205.00	Xolair [NV]

COUGH AND COLD PREPARATIONS

EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

Mucolytics

DORNASE ALFA

Note This drug is not PBS-subsidised for use in combination with PBS-subsidised mannitol.

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

Authority required (STREAMLINED)

5740

Cystic fibrosis

Population criteria:

Patient must be 5 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Authority required (STREAMLINED)

5634

Cystic fibrosis

Clinical criteria:

Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR

Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR

Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR

Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.

Population criteria:

Patient must be less than 5 years of age.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented. Treatment with this drug should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.

Authority required (STREAMLINED)

5635

Cystic fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have initiated treatment with dornase alfa at an age of less than 5 years, AND

Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

Population criteria:

Patient must be 5 years of age or older.

Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

dornase alfa 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules

5704F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	..	*2242.00	Pulmozyme [RO]

▪ MANNITOL

Note This drug is not PBS-subsidised for use in combination with PBS-subsidised dornase alfa.

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

Authority required (STREAMLINED)

5799

Cystic fibrosis

Clinical criteria:

Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result, AND

Patient must be intolerant or inadequately responsive to dornase alfa.

Population criteria:

Patient must be 6 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

MANNITOL Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers, 1

2015C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	5	..	*1736.00	bronchitol [XA]

▪ OTHER RESPIRATORY SYSTEM PRODUCTS

OTHER RESPIRATORY SYSTEM PRODUCTS

Other respiratory system products

▪ IVACAFTOR

Note Special Pricing Arrangements apply.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment – New patients

Clinical criteria:

Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, AND

Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR

Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, AND

Patient must not receive more than 24 weeks of treatment under this restriction, AND

The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

Patient must be 6 years of age or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Cystic Fibrosis Ivacaftor Authority Application Supporting Information Form; and

(3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and

(4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene; and

(5) the result of a FEV1 measurement performed within a month prior to the date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and

(6) evidence that the patient has either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities; and

(7) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and

(8) a copy of a sweat chloride result; and

(9) height and weight measurements at the time of application; and

(10) a baseline measurement of the number of days of CF-related hospitalisation (including hospital-in-the home) in the previous 12 months.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, AND

Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, AND

Patient must not receive more than 24 weeks of treatment under this restriction, AND

The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

Patient must be 6 years of age or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Patients who have an acute infective exacerbation at the time of assessment for continuing therapy may receive an additional one month's supply in order to enable the assessment to be repeated following resolution of the exacerbation.

Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Cystic Fibrosis Ivacaftor Authority Continuing Application Supporting Information Form; and

(3) the result of a FEV1 measurement performed within one month prior to the date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and

(4) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and

(5) a recent sweat chloride result; and

(6) height and weight measurements at the time of application; and

(7) a measurement of number of days of CF-related hospitalisation (including hospital in the home) in the previous 6 months.

Authority required

Cystic fibrosis

Treatment Phase: Initial treatment - Grandfather patients

Clinical criteria:

Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, AND

Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR

Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, AND

Patient must have received treatment with ivacaftor for this condition prior to 1 December 2014, AND

Patient must have received treatment with ivacaftor within the last 6 months at the time of application, AND

Patient must not receive more than 24 weeks of treatment under this restriction, AND

The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

Patient must be 6 years of age or older.

Patients receiving PBS-subsidised ivacaftor must be registered in the Australian Cystic Fibrosis Database Registry.

Treatment must not be given to a patient who has an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing this drug.

Dosage of ivacaftor must not exceed the dose of 150 mg twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of 150 mg daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Cystic Fibrosis Ivacaftor Application Supporting Information Form; and

(3) a signed patient acknowledgement; or an acknowledgement signed by a parent or authorised guardian, if applicable; and

(4) a copy of the pathology report detailing the molecular testing for G551D mutation or other gating (class III) mutation on the CFTR gene performed prior to commencing treatment with ivacaftor; and

(5) the result of a FEV1 measurement performed prior to commencing treatment with ivacaftor for this condition; and

(6) the result of a FEV1 measurement performed within a month prior to date of application. Note: FEV1, must be measured in an accredited pulmonary function laboratory, with documented no acute infective exacerbation at the time FEV1 is measured; and

(7) evidence that the patient had either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities prior to commencing treatment with ivacaftor for this condition; and

(8) a copy of a current medication history, including any CYP3A4 inhibitors and/or CYP3A4 inducers; and

(9) a copy of sweat chloride result performed prior to commencing treatment with ivacaftor for this condition; and

(10) a recent sweat chloride result prior to commencing PBS-subsidised ivacaftor; and

(11) height and weight measurements at the time of application; and

(12) height and weight measurements performed immediately prior to commencement of ivacaftor; and

(13) a baseline measurement of number of days of CF-related hospitalisation (including hospital-in-the home) in the 12 months prior to commencement of ivacaftor; and

(14) a measurement of the number of days of CF-related hospitalisation (including hospital-in the home) in the 6 months prior to the date of application; and

(15) dates of prior ivacaftor therapy.

ivacaftor 150 mg tablet, 56

10170G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	..	22500.00	Kalydeco [VR]

▪ VARIOUS

▪ ALL OTHER THERAPEUTIC PRODUCTS

ALL OTHER THERAPEUTIC PRODUCTS

Iron chelating agents

▪ DEFERASIROX

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

3828

Chronic iron overload in patients with disorders of erythropoiesis

deferasirox 125 mg tablet: dispersible, 28

5654N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	5	..	*1331.40	Exjade [NV]

deferasirox 250 mg tablet: dispersible, 28

5655P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	5	..	*2662.74	Exjade [NV]

deferasirox 500 mg tablet: dispersible, 28

5656Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	5	..	*5325.54	Exjade [NV]

▪ DEFERIPRONE

Authority required (STREAMLINED)

3338

Iron overload in patients with thalassaemia major who are unable to take desferrioxamine therapy

Authority required (STREAMLINED)

3339

Iron overload in patients with thalassaemia major in whom desferrioxamine therapy has proven ineffective

deferiprone 100 mg/mL oral liquid, 250 mL

5658T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	5	5	..	*1070.10	Ferriprox [TX]

deferiprone 500 mg tablet, 100

5657R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	5	..	*2568.18	Ferriprox [TX]

▪ DESFERRIOXAMINE

Authority required (STREAMLINED)

3340

Disorders of erythropoiesis associated with treatment-related chronic iron overload

desferrioxamine mesylate 2 g injection, 1 vial

5661Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	60	5	..	*1724.40	Hospira Pty Limited [HH]

desferrioxamine mesylate 500 mg injection, 10 vials

5662B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	40	5	..	*6746.40	Hospira Pty Limited [HH]

Drugs for treatment of hyperkalemia and hyperphosphatemia

▪ LANTHANUM

Authority required (STREAMLINED)

5530

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

Clinical criteria:

The condition must not be adequately controlled by calcium, AND

Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR

The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND

The treatment must not be used in combination with any other non-calcium phosphate binding agents.

Treatment criteria:

Patient must be undergoing dialysis for chronic kidney disease.

LANTHANUM Tablet, chewable, 1000 mg (as carbonate hydrate), 90

5782H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*845.52	Fosrenol [ZI]

LANTHANUM Tablet, chewable, 500 mg (as carbonate hydrate), 90

5780F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*497.36	Fosrenol [ZI]

LANTHANUM Tablet, chewable, 750 mg (as carbonate hydrate), 90

5781G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*751.04	Fosrenol [ZI]

▪ SEVELAMER

Authority required (STREAMLINED)

5530

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

Clinical criteria:

The condition must not be adequately controlled by calcium, AND

Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR

The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND

The treatment must not be used in combination with any other non-calcium phosphate binding agents.

Treatment criteria:

Patient must be undergoing dialysis for chronic kidney disease.

sevelamer hydrochloride 800 mg tablet, 180

9546K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	..	*589.00	Renagel [GZ]

▪ SUCROFERRIC OXYHYDROXIDE

Authority required (STREAMLINED)

5530

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

Clinical criteria:

The condition must not be adequately controlled by calcium, AND

Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR

The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, AND

The treatment must not be used in combination with any other non-calcium phosphate binding agents.

Treatment criteria:

Patient must be undergoing dialysis for chronic kidney disease.

iron (as sucroferric oxyhydroxide) 500 mg tablet: chewable, 90

10233N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	..	*753.46	Velphoro [FN]

Highly Specialised Drugs Program (Community Access)

ANTIINFECTIVES FOR SYSTEMIC USE

ANTIVIRALS FOR SYSTEMIC USE

DIRECT ACTING ANTIVIRALS

Nucleosides and nucleotides excl. reverse transcriptase inhibitors

GANCICLOVIR

Authority required (STREAMLINED)

5000

Cytomegalovirus retinitis

Clinical criteria:

Patient must be severely immunocompromised, inculding due to HIV infection.

ganciclovir 500 mg injection, 5 vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10328N	2	1	..	*560.21	38.30	Cymevene [RO]

VALGANCICLOVIR

Authority required (STREAMLINED)

4980

Cytomegalovirus retinitis

Clinical criteria:

Patient must have HIV infection.

HSD (Community)

valganciclovir 450 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10306K	2	5	..	*4313.95	38.30	Valcyte [RO]

valganciclovir 50 mg/mL oral liquid: powder for, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10277X	11	5	..	*#4395.72	38.30	Valcyte [RO]

Phosphonic acid derivatives

FOSCARNET

Authority required (STREAMLINED)

4980

Cytomegalovirus retinitis

Clinical criteria:

Patient must have HIV infection.

Authority required (STREAMLINED)

4973

Herpes simplex virus infection

Clinical criteria:

The condition must be aciclovir resistant, AND

Patient must have HIV infection.

FOSCARNET SODIUM I.V. infusion 24 mg per mL, 250 mL bottle, 6

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10352W	1	1	..	1165.56	38.30	Foscavir [IX]

Protease inhibitors

ATAZANAVIR

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive, AND

The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection, AND

The treatment must be in combination with other antiretroviral agents.

atazanavir 150 mg capsule, 60

10276W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*1038.21	38.30	Reyataz [BQ]

atazanavir 200 mg capsule, 60

10349Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*1369.11	38.30	Reyataz [BQ]

atazanavir 300 mg capsule, 30

10321F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*1038.21	38.30	Reyataz [BQ]

▪ ATAZANAVIR + COBICISTAT

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive, AND

The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection, AND

The treatment must be in combination with other antiretroviral agents.

atazanavir 300 mg + cobicistat 150 mg tablet, 30

10692R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*1116.35	38.30	Evotaz [BQ]

▪ DARUNAVIR

Authority required (STREAMLINED)

5094

Human immunodeficiency virus (HIV) infection

Clinical criteria:

The treatment must be in addition to optimised background therapy, AND

The treatment must be in combination with other antiretroviral agents, AND

The treatment must be co-administered with 100 mg ritonavir twice daily, AND

Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

darunavir 150 mg tablet, 240

10287K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	1043.05	38.30	Prezista [JC]

darunavir 600 mg tablet, 60

10329P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*2039.47	38.30	Prezista [JC]

▪ DARUNAVIR

Authority required (STREAMLINED)

4313

Human immunodeficiency virus (HIV) infection

Clinical criteria:

The treatment must be in addition to optimised background therapy, AND

The treatment must be in combination with other antiretroviral agents, AND

The treatment must be co-administered with 100 mg ritonavir, AND

Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen, AND

Patient must not have demonstrated darunavir resistance associated mutations detected on resistance testing.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

darunavir 800 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10367P	2	5	..	*1375.29	38.30	Prezista [JC]

▪ FOSAMPRENAVIR

Authority required (STREAMLINED)
4512
HIV infection
Treatment Phase: Initial
Clinical criteria:
Patient must be antiretroviral treatment naive, AND
The treatment must be in combination with other antiretroviral agents.
Authority required (STREAMLINED)
4454
HIV infection
Treatment Phase: Continuing
Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection, AND
The treatment must be in combination with other antiretroviral agents.

fosamprenavir 700 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10337C	2	5	..	*756.15	38.30	Telzir [VI]

▪ INDINAVIR

Authority required (STREAMLINED)
4512
HIV infection
Treatment Phase: Initial
Clinical criteria:
Patient must be antiretroviral treatment naive, AND
The treatment must be in combination with other antiretroviral agents.
Authority required (STREAMLINED)
4454
HIV infection
Treatment Phase: Continuing
Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection, AND
The treatment must be in combination with other antiretroviral agents.

indinavir 400 mg capsule, 180

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10363K	2	5	..	*906.01	38.30	Crixivan 400 mg [MK]

▪ RITONAVIR

Authority required (STREAMLINED)
4512
HIV infection
Treatment Phase: Initial
Clinical criteria:
Patient must be antiretroviral treatment naive, AND
The treatment must be in combination with other antiretroviral agents.
Authority required (STREAMLINED)
4454
HIV infection
Treatment Phase: Continuing
Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection, AND
The treatment must be in combination with other antiretroviral agents.

ritonavir 100 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10273Q	24	5	..	*977.97	38.30	Norvir [VE]

ritonavir 600 mg/7.5 mL oral liquid, 90 mL

10300D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	10	5	..	*906.03	38.30	Norvir [VE]

▪ SAQUINAVIR

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive, AND

The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection, AND

The treatment must be in combination with other antiretroviral agents.

saquinavir 500 mg tablet, 120

10335Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*1005.91	38.30	Invirase [RO]

▪ TIPRANAVIR

Authority required (STREAMLINED)

5764

HIV infection

Clinical criteria:

The treatment must be in addition to optimised background therapy, AND

The treatment must be in combination with other antiretroviral agents, AND

Patient must be antiretroviral experienced, AND

The treatment must be co-administered with 200 mg ritonavir twice daily, AND

Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

tipranavir 250 mg capsule, 120

10344K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*1674.85	38.30	Aptivus [BY]

Nucleoside and nucleotide reverse transcriptase inhibitors

▪ ABACAVIR

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive, AND

The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection, AND

The treatment must be in combination with other antiretroviral agents.

abacavir 20 mg/mL oral liquid, 240 mL

10356C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	8	5	..	*656.13	38.30	Ziagen [VI]

abacavir 300 mg tablet, 60

10294T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*564.17	38.30	Ziagen [VI]

▪ ADEFOVIR DIPIVOXIL

Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

Authority required (STREAMLINED)

4490

Chronic hepatitis B infection

Clinical criteria:

Patient must not have cirrhosis, AND

Patient must have failed antihepadnaviral therapy, AND

Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR

Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.

Authority required (STREAMLINED)

4510

Chronic hepatitis B infection

Clinical criteria:

Patient must have cirrhosis, AND

Patient must have failed antihepadnaviral therapy, AND

Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

HSD (Community)

adefovir dipivoxil 10 mg tablet, 30

10290N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*1096.93	38.30	[a] APO-Adefovir [TX]	[a] Hepsera [GI]

▪ DIDANOSINE

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive, AND

The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection, AND

The treatment must be in combination with other antiretroviral agents.

didanosine 125 mg capsule: enteric, 30

10350R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*284.43	38.30	Videx EC [BQ]

didanosine 200 mg capsule: enteric, 30

10351T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*329.81	38.30	Videx EC [BQ]

didanosine 250 mg capsule: enteric, 30

10364L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*410.51	38.30	Videx EC [BQ]

didanosine 400 mg capsule: enteric, 30

10313T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*652.67	38.30	Videx EC [BQ]

▪ EMTRICITABINE

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive, AND

The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection, AND

The treatment must be in combination with other antiretroviral agents.

emtricitabine 200 mg capsule, 30

10274R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*564.17	38.30	Emtriva [GI]

▪ ENTECAVIR

Authority required (STREAMLINED)

4993

Chronic hepatitis B infection

Clinical criteria:

Patient must not have cirrhosis, AND

Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR

Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, AND

Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.

Authority required (STREAMLINED)

5036

Chronic hepatitis B infection

Clinical criteria:

Patient must have cirrhosis, AND

Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

entecavir monohydrate 500 microgram tablet, 30

10279B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*766.31	38.30	Baraclude [BQ]

▪ ENTECAVIR

Note PBS-subsidised entecavir monohydrate must be used as monotherapy.

Authority required (STREAMLINED)

5044

Chronic hepatitis B infection

Clinical criteria:

Patient must not have cirrhosis, AND

Patient must have failed lamivudine, AND

Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR

Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.

Authority required (STREAMLINED)

5037

Chronic hepatitis B infection

Clinical criteria:

Patient must have cirrhosis, AND

Patient must have failed lamivudine, AND

Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

entecavir monohydrate 1 mg tablet, 30

10353X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*1234.43	38.30	Baraclude [BQ]

▪ LAMIVUDINE

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive, AND

The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection, AND

The treatment must be in combination with other antiretroviral agents.

lamivudine 10 mg/mL oral liquid, 240 mL

10320E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*472.69	38.30	3TC [VI]

lamivudine 150 mg tablet, 60

10348P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*257.23	38.30	[a] 3TC [VI] [a] Lamivudine RBX [RA]	[a] Lamivudine Alphapharm [AF]

lamivudine 300 mg tablet, 30

10311Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*257.23	38.30	[a] 3TC [VI] [a] Lamivudine RBX [RA]	[a] Lamivudine Alphapharm [AF]

HSD (Community)

▪ LAMIVUDINE

Authority required (STREAMLINED)

4993

Chronic hepatitis B infection

Clinical criteria:

Patient must not have cirrhosis, AND

Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR

Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, AND

Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.

Authority required (STREAMLINED)

5036

Chronic hepatitis B infection

Clinical criteria:

Patient must have cirrhosis, AND

Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

lamivudine 100 mg tablet, 28

10315X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*139.51	38.30	[a] Zeffix [RW]	[a] Zetlam [AF]

lamivudine 5 mg/mL oral liquid, 240 mL

10338D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5	5	..	*242.23	38.30	Zeffix [RW]

▪ STAVUDINE

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive, AND

The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection, AND

The treatment must be in combination with other antiretroviral agents.

stavudine 30 mg capsule, 60

10271N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*666.29	38.30	Zerit [BQ]

stavudine 40 mg capsule, 60

10312R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*886.07	38.30	Zerit [BQ]

▪ TELBIVUDINE

Authority required (STREAMLINED)

4994

Chronic hepatitis B infection

Clinical criteria:

Patient must have cirrhosis, AND

Patient must be nucleoside analogue naive, AND

Patient must have detectable HBV DNA, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Authority required (STREAMLINED)

4995

Chronic hepatitis B infection

Clinical criteria:

Patient must not have cirrhosis, AND

Patient must be nucleoside analogue naive, AND

Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR

Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, AND

Patient must have evidence of chronic liver injury determined by: (i) confirmed elevated serum ALT; or (ii) liver biopsy, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

telbivudine 600 mg tablet, 28

10372X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*502.67	38.30	Sebivo [NV]

▪ TENOFOVIR

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive, AND

The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection, AND

The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4476

Chronic hepatitis B infection

Clinical criteria:

Patient must have cirrhosis, AND

Patient must be nucleoside analogue naive, AND

Patient must have detectable HBV DNA, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

Authority required (STREAMLINED)

4489

Chronic hepatitis B infection

Clinical criteria:

Patient must not have cirrhosis, AND

Patient must be nucleoside analogue naive, AND

Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR

Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, AND

Patient must have evidence of chronic liver injury determined by: (i) confirmed elevated serum ALT; or (ii) liver biopsy, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

Authority required (STREAMLINED)

4510

Chronic hepatitis B infection

Clinical criteria:

Patient must have cirrhosis, AND

Patient must have failed antihepadnaviral therapy, AND

Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

Authority required (STREAMLINED)

4490

Chronic hepatitis B infection

Clinical criteria:

Patient must not have cirrhosis, AND

Patient must have failed antihepadnaviral therapy, AND

Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR

Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.

Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

tenofovir disoproxil fumarate 300 mg tablet, 30

10310P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*961.55	38.30	Viread [GI]

▪ ZIDOVUDINE

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive, AND

The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection, AND

The treatment must be in combination with other antiretroviral agents.

zidovudine 100 mg capsule, 100

10266H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	5	..	*818.93	38.30	Retrovir [VI]

zidovudine 250 mg capsule, 40

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10360G	6	5	..	*1218.09	38.30	Retrovir [VI]

zidovudine 50 mg/5 mL oral liquid, 200 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10361H	15	5	..	*672.18	38.30	Retrovir [VI]

Non-nucleoside reverse transcriptase inhibitors

▪ EFAVIRENZ

Authority required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must be antiretroviral treatment naive, AND

The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

Patient must have previously received PBS-subsidised therapy for HIV infection, AND

The treatment must be in combination with other antiretroviral agents.

efavirenz 200 mg tablet, 90

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10336B	2	5	..	*543.57	38.30	Stocrin [MK]

efavirenz 30 mg/mL oral liquid, 180 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10275T	7	5	..	*570.43	38.30	Stocrin [MK]

efavirenz 600 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10366N	2	5	..	*543.57	38.30	Stocrin [MK]

▪ ETRAVIRINE

Authority required (STREAMLINED)

5014

HIV infection

Clinical criteria:

The treatment must be in addition to optimised background therapy, AND

The treatment must be in combination with other antiretroviral agents, AND

Patient must be antiretroviral experienced, AND

Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

etravirine 200 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10301E	2	5	..	*1218.29	38.30	Intelence [JC]

▪ NEVIRAPINE

Authority required (STREAMLINED)

4526

HIV infection

Treatment Phase: Initial

Clinical criteria:

Patient must have been stabilised on nevirapine immediate release, AND

The treatment must be in combination with other antiretroviral agents.

Authority required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection, AND
The treatment must be in combination with other antiretroviral agents.

nevirapine 400 mg tablet: modified release, 30

10303G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*333.79	38.30	Viramune XR [BY]

▪ NEVIRAPINE

Authority required (STREAMLINED)
4512
HIV infection
Treatment Phase: Initial
Clinical criteria:
Patient must be antiretroviral treatment naive, AND
The treatment must be in combination with other antiretroviral agents.
Authority required (STREAMLINED)
4454
HIV infection
Treatment Phase: Continuing
Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection, AND
The treatment must be in combination with other antiretroviral agents.

nevirapine 10 mg/mL oral liquid, 240 mL

10319D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10	5	..	*1396.93	38.30	Viramune [BY]

nevirapine 200 mg tablet, 60

10304H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	..	*333.79	38.30	[a] Nevipin [EA] [a] Nevirapine RBX [RA]	[a] Nevirapine Alphapharm [AF] [a] Viramune [BY]

▪ RILPIVIRINE

Authority required (STREAMLINED)
4512
HIV infection
Treatment Phase: Initial
Clinical criteria:
Patient must be antiretroviral treatment naive, AND
The treatment must be in combination with other antiretroviral agents.
Authority required (STREAMLINED)
4454
HIV infection
Treatment Phase: Continuing
Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection, AND
The treatment must be in combination with other antiretroviral agents.

rilpivirine 25 mg tablet, 30

10298B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*571.81	38.30	Edurant [JC]

Antivirals for treatment of HIV infections, combinations

▪ ABACAVIR + LAMIVUDINE

Authority required (STREAMLINED)
4527
HIV infection
Treatment Phase: Initial
Clinical criteria:
Patient must be antiretroviral treatment naive, AND
The treatment must be in combination with other antiretroviral agents.
Population criteria:
Patient must be aged 12 years or older, AND
Patient must weigh 40 kg or more.
Authority required (STREAMLINED)
4528

HIV infection
Treatment Phase: Continuing
Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection, AND
The treatment must be in combination with other antiretroviral agents.
Population criteria:
Patient must be aged 12 years or older, AND
Patient must weigh 40 kg or more.

abacavir 600 mg + lamivudine 300 mg tablet, 30

10357D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*814.47	38.30	Kivexa [VI]

▪ ABACAVIR + LAMIVUDINE + ZIDOVUDINE

Authority required (STREAMLINED)
4495
HIV infection
Treatment Phase: Initial
Clinical criteria:
Patient must be antiretroviral treatment naive.
Population criteria:
Patient must be aged 12 years or older, AND
Patient must weigh 40 kg or more.
Authority required (STREAMLINED)
4480
HIV infection
Treatment Phase: Continuing
Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection.
Population criteria:
Patient must be aged 12 years or older, AND
Patient must weigh 40 kg or more.

abacavir 300 mg + lamivudine 150 mg + zidovudine 300 mg tablet, 60

10305J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*1305.25	38.30	Trizivir [VI]

▪ DOLUTEGRAVIR + ABACAVIR + LAMIVUDINE

Authority required (STREAMLINED)
4495
HIV infection
Treatment Phase: Initial
Clinical criteria:
Patient must be antiretroviral treatment naive.
Population criteria:
Patient must be aged 12 years or older, AND
Patient must weigh 40 kg or more.
Authority required (STREAMLINED)
4480
HIV infection
Treatment Phase: Continuing
Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection.
Population criteria:
Patient must be aged 12 years or older, AND
Patient must weigh 40 kg or more.

dolutegravir 50 mg + abacavir 600 mg + lamivudine 300 mg tablet, 30

10345L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*2031.59	38.30	Triumeq [VI]

▪ LAMIVUDINE + ZIDOVUDINE

Authority required (STREAMLINED)
4512
HIV infection
Treatment Phase: Initial

Clinical criteria:
Patient must be antiretroviral treatment naive, AND
The treatment must be in combination with other antiretroviral agents.
Authority required (STREAMLINED)
4454
HIV infection
Treatment Phase: Continuing
Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection, AND
The treatment must be in combination with other antiretroviral agents.

lamivudine 150 mg + zidovudine 300 mg tablet, 60

10284G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*771.57	38.30	[a] Combivir [VI]	[a] Lamivudine 150 mg + Zidovudine 300 mg Alphapharm [AF]

▪ LOPINAVIR + RITONAVIR

Authority required (STREAMLINED)
4512
HIV infection
Treatment Phase: Initial
Clinical criteria:
Patient must be antiretroviral treatment naive, AND
The treatment must be in combination with other antiretroviral agents.
Authority required (STREAMLINED)
4454
HIV infection
Treatment Phase: Continuing
Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection, AND
The treatment must be in combination with other antiretroviral agents.

lopinavir 100 mg + ritonavir 25 mg tablet, 60

10285H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*360.99	38.30	Kaletra [VE]

lopinavir 200 mg + ritonavir 50 mg tablet, 120

10272P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*1408.71	38.30	Kaletra [VE]

lopinavir 80 mg/mL + ritonavir 20 mg/mL oral liquid, 60 mL

10327M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	10	5	..	*1329.33	38.30	Kaletra [VE]

▪ TENOFOVIR + EMTRICITABINE

Authority required (STREAMLINED)
4512
HIV infection
Treatment Phase: Initial
Clinical criteria:
Patient must be antiretroviral treatment naive, AND
The treatment must be in combination with other antiretroviral agents.
Authority required (STREAMLINED)
4454
HIV infection
Treatment Phase: Continuing
Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection, AND
The treatment must be in combination with other antiretroviral agents.

tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30

10347N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*1500.63	38.30	Truvada [GI]

▪ TENOFOVIR + EMTRICITABINE + EFAVIRENZ

Authority required (STREAMLINED)

4522
HIV infection
Treatment Phase: Initial
Clinical criteria:
Patient must be antiretroviral treatment naive.
Authority required (STREAMLINED)
4470
HIV infection
Treatment Phase: Continuing
Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection.

tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + efavirenz 600 mg tablet, 30

10297Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*2016.63	38.30	Atripla [GI]

▪ TENOFOVIR + EMTRICITABINE + ELVITEGRAVIR + COBICISTAT

Authority required (STREAMLINED)
4522
HIV infection
Treatment Phase: Initial
Clinical criteria:
Patient must be antiretroviral treatment naive.
Authority required (STREAMLINED)
4470
HIV infection
Treatment Phase: Continuing
Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection.

tenofovir alafenamide 10 mg + emtricitabine 200 mg + elvitegravir 150 mg + cobicistat 150 mg tablet, 30

10680D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*2016.63	38.30	Genvoya [GI]

tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + elvitegravir 150 mg + cobicistat 150 mg tablet, 30

10307L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*2016.63	38.30	Stribild [GI]

▪ TENOFOVIR + EMTRICITABINE + RILPIVIRINE

Authority required (STREAMLINED)
4522
HIV infection
Treatment Phase: Initial
Clinical criteria:
Patient must be antiretroviral treatment naive.
Authority required (STREAMLINED)
4470
HIV infection
Treatment Phase: Continuing
Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection.

tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + rilpivirine 25 mg tablet, 30

10314W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*2043.79	38.30	Eviplera [GI]

Other antivirals

▪ DOLUTEGRAVIR

Authority required (STREAMLINED)
4512
HIV infection
Treatment Phase: Initial
Clinical criteria:
Patient must be antiretroviral treatment naive, AND
The treatment must be in combination with other antiretroviral agents.
Authority required (STREAMLINED)

4454
HIV infection
Treatment Phase: Continuing
Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection, AND
The treatment must be in combination with other antiretroviral agents.

dolutegravir 50 mg tablet, 30

10283F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*1378.03	38.30	Tivicay [VI]

▪ ENFUVIRTIDE

Authority required (STREAMLINED)
5014
HIV infection
Clinical criteria:
The treatment must be in addition to optimised background therapy, AND
The treatment must be in combination with other antiretroviral agents, AND
Patient must be antiretroviral experienced, AND
Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes.
Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

enfuvirtide 90 mg injection [60 vials] (&) inert substance diluent [60 x 1.1 mL vials], 1 pack

10365M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*4251.63	38.30	Fuzeon [RO]

▪ MARAVIROC

Authority required (STREAMLINED)
5008
HIV infection
Clinical criteria:
Patient must be infected with CCR5-tropic HIV-1, AND
The treatment must be in addition to optimised background therapy, AND
The treatment must be in combination with other antiretroviral agents, AND
Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes.
Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.
A tropism assay to determine CCR5 only strain status must be performed prior to initiation. Individuals with CXCR4 tropism demonstrated at any time point are not eligible.

maraviroc 150 mg tablet, 60

10318C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*1790.57	38.30	Celsentri [VI]

maraviroc 300 mg tablet, 60

10355B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*1790.57	38.30	Celsentri [VI]

▪ RALTEGRAVIR

Authority required (STREAMLINED)
4512
HIV infection
Treatment Phase: Initial
Clinical criteria:
Patient must be antiretroviral treatment naive, AND
The treatment must be in combination with other antiretroviral agents.
Authority required (STREAMLINED)
4454
HIV infection
Treatment Phase: Continuing
Clinical criteria:
Patient must have previously received PBS-subsidised therapy for HIV infection, AND
The treatment must be in combination with other antiretroviral agents.

raltegravir 400 mg tablet, 60

10286J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*1311.47	38.30	Isentress [MK]

▪ RALTEGRAVIR

Authority required (STREAMLINED)

4275

HIV infection

Treatment Phase: Initial

Clinical criteria:

The treatment must be in combination with other antiretroviral agents, AND

Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy, AND

Patient must have a CD4 count of less than 500 per cubic millimetre; OR

Patient must have symptomatic HIV disease.

Population criteria:

Patient must be aged 2 years or older.

Authority required (STREAMLINED)

4274

HIV infection

Treatment Phase: Continuing

Clinical criteria:

The treatment must be in combination with other antiretroviral agents, AND

Patient must be antiretroviral experienced with at least 6 months therapy with 2 alternate classes of anti-retroviral therapy, AND

Patient must have previously received PBS-subsidised therapy for HIV infection.

Population criteria:

Patient must be aged 2 years or older.

raltegravir 100 mg tablet: chewable, 60

10326L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
6	5	..	*1970.73	38.30	Isentress [MK]

raltegravir 25 mg tablet: chewable, 60

10299C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
6	5	..	*507.15	38.30	Isentress [MK]

▪ ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

▪ IMMUNOSTIMULANTS

IMMUNOSTIMULANTS

Interferons

▪ INTERFERON ALFA-2A

Authority required (STREAMLINED)

4993

Chronic hepatitis B infection

Clinical criteria:

Patient must not have cirrhosis, AND

Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR

Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, AND

Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.

Authority required (STREAMLINED)

5036

Chronic hepatitis B infection

Clinical criteria:

Patient must have cirrhosis, AND

Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe

10317B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	30	5	..	*890.13	38.30	Roferon-A [RO]

interferon alfa-2a 4.5 million units/0.5 mL injection, 0.5 mL syringe

10371W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	30	5	..	*1320.93	38.30	Roferon-A [RO]

interferon alfa-2a 6 million units/0.5 mL injection, 0.5 mL syringe

10354Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	30	5	..	*1744.83	38.30	Roferon-A [RO]

interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe

10369R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	30	5	..	*2594.13	38.30	Roferon-A [RO]

▪ INTERFERON ALFA-2B

Authority required (STREAMLINED)

4993

Chronic hepatitis B infection

Clinical criteria:

Patient must not have cirrhosis, AND

Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR

Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, AND

Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.

Authority required (STREAMLINED)

5036

Chronic hepatitis B infection

Clinical criteria:

Patient must have cirrhosis, AND

Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

interferon alfa-2b 10 million units/mL injection, 5 x 1 mL vials

10370T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	3	5	..	*1461.96	38.30	Intron A [MK]

interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL cartridge

10291P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*360.11	38.30	Intron A Redipen [MK]

interferon alfa-2b 18 million units/3 mL injection, 3 mL vial

10340F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	15	5	..	*2593.98	38.30	Intron A [MK]

interferon alfa-2b 25 million units/2.5 mL injection, 2.5 mL vial

10339E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	15	5	..	*3584.58	38.30	Intron A [MK]

interferon alfa-2b 30 million units/1.2 mL injection, 1.2 mL cartridge

10316Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*595.59	38.30	Intron A Redipen [MK]

interferon alfa-2b 60 million units/1.2 mL injection, 1.2 mL cartridge

10292Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*1178.95	38.30	Intron A Redipen [MK]

▪ PEGINTERFERON ALFA-2A

Caution Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Authority required (STREAMLINED)

5010

Chronic hepatitis B infection

Clinical criteria:

Patient must not have cirrhosis, AND

Patient must not have previously received peginterferon alfa therapy for the treatment of hepatitis B, AND

Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR

Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, AND

Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy, AND

The treatment must be the sole PBS-subsidised therapy for this condition.

Authority required (STREAMLINED)

5067

Chronic hepatitis B infection

Clinical criteria:

Patient must have cirrhosis, AND

Patient must have detectable HBV DNA, AND

The treatment must be the sole PBS-subsidised therapy for this condition, AND

The treatment must be limited to 1 course of treatment for a maximum duration of 48 weeks.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes

10280C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*2262.15	38.30	Pegasys [RO]

peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes

10278Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*2612.37	38.30	Pegasys [RO]

HSD (Community)

▪ NERVOUS SYSTEM

▪ PSYCHOLEPTICS

ANTIPSYCHOTICS

Diazepines, oxazepines, thiazepines and oxepines

▪ CLOZAPINE

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Novartis Clozaril Patient Monitoring System (eCPMS) or Hospira Clopineconnect.

Authority required (STREAMLINED)

4998

Schizophrenia

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received PBS-subsidised therapy with this drug for this condition, AND

Patient must have completed at least 18 weeks therapy, AND

Patient must be on a clozapine dosage considered stable by a treating psychiatrist, AND

The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals.

Treatment criteria:

Must be treated by a psychiatrist; OR

Must be treated by an authorised medical practitioner, with the agreement of the treating psychiatrist.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

clozapine 100 mg tablet, 100

10358E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	..	..	*259.01	38.30	[a] Clopine 100 [HH]	[a] Clozaril 100 [NV]

clozapine 200 mg tablet, 100

10288L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*511.09	38.30	Clopine 200 [HH]

clozapine 25 mg tablet, 100

10289M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*75.57	38.30	[a] Clopine 25 [HH]	[a] Clozaril 25 [NV]

clozapine 50 mg tablet, 100

10302F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*141.39	38.30	Clopine 50 [HH]

clozapine 50 mg/mL oral liquid, 100 mL

10341G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	147.33	38.30	Clopine Suspension [HH]

Botulinum Toxin Program

MUSCULO-SKELETAL SYSTEM

MUSCLE RELAXANTS

MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS

Other muscle relaxants, peripherally acting agents

BOTULINUM TOXIN TYPE A

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)

5221

Blepharospasm or hemifacial spasm
Clinical criteria:
Patient must have blepharospasm; OR
Patient must have hemifacial spasm.
Population criteria:
Patient must be aged 12 years or older.
Treatment criteria:
Must be treated by a neurologist; OR
Must be treated by an ophthalmologist; OR
Must be treated by an otolaryngology head and neck surgeon; OR
Must be treated by a plastic surgeon.

Authority required (STREAMLINED)

5359

Dynamic equinus foot deformity
Clinical criteria:
The condition must be due to spasticity, AND
Patient must have cerebral palsy, AND
Patient must be ambulant.
Population criteria:
Patient must be aged from 2 to 17 years inclusive.
Treatment criteria:
Must be treated by a neurologist; OR
Must be treated by an orthopaedic surgeon; OR
Must be treated by a paediatrician; OR
Must be treated by a rehabilitation specialist.

Authority required (STREAMLINED)

5407

Dynamic equinus foot deformity
Clinical criteria:
The condition must be due to spasticity, AND
Patient must have cerebral palsy, AND
Patient must be ambulant, AND
Patient must have commenced PBS-subsidised treatment with Botulinum Toxin Type A Purified Neurotoxin Complex as a paediatric patient.
Population criteria:
Patient must be aged 18 years or older.
Treatment criteria:
Must be treated by a neurologist; OR
Must be treated by an orthopaedic surgeon; OR
Must be treated by a paediatrician; OR
Must be treated by a rehabilitation specialist.

Authority required (STREAMLINED)

5406

Spasmodic torticollis
Clinical criteria:
Patient must have spasmodic torticollis, AND
The treatment must be as monotherapy; OR
The treatment must be as adjunctive therapy to current standard care.
Treatment criteria:
Must be treated by a neurologist; OR
Must be treated by a plastic surgeon; OR
Must be treated by a rehabilitation specialist.

Authority required (STREAMLINED)

5178

Moderate to severe spasticity of the upper limb

Clinical criteria:

Patient must have cerebral palsy.

Population criteria:

Patient must be aged from 2 to 17 years inclusive.

Treatment criteria:

Must be treated by a neurologist; OR

Must be treated by an orthopaedic surgeon; OR

Must be treated by a paediatrician; OR

Must be treated by a rehabilitation specialist; OR

Must be treated by a plastic surgeon.

Authority required (STREAMLINED)

5261

Moderate to severe spasticity of the upper limb

Clinical criteria:

Patient must have cerebral palsy, AND

Patient must have commenced PBS-subsidised treatment with Botulinum Type A Neurotoxin Complex as a paediatric patient.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a neurologist; OR

Must be treated by an orthopaedic surgeon; OR

Must be treated by a paediatrician; OR

Must be treated by a rehabilitation specialist; OR

Must be treated by a plastic surgeon.

Note Contact the Department of Human Services before commencing PBS-subsidised treatment in cerebral palsy patients who have been treated for moderate to severe spasticity of the upper limb with non-PBS-subsidised botulinum toxin prior to the age of 18.

Authority required (STREAMLINED)

5220

Moderate to severe spasticity of the upper limb following a stroke

Clinical criteria:

The condition must be moderate to severe spasticity of the upper limb/s following stroke, defined as a Modified Ashworth Scale rating of 3 or more, AND

The treatment must not be initiated until three months post-stroke, AND

The treatment must only be used as second line therapy when standard management has failed; OR

The treatment must only be used as an adjunct to physical therapy, AND

The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (total Botox, Dysport, and Xeomin), AND

The treatment must not exceed 4 treatment periods (total Botox, Dysport, and Xeomin) per upper limb per lifetime, AND

Patient must not have established severe contracture in the limb to be treated.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a neurologist; OR

Must be treated by an orthopaedic surgeon; OR

Must be treated by a rehabilitation specialist; OR

Must be treated by a plastic surgeon; OR

Must be treated by a geriatrician.

The date of the stroke must be documented in the patient's medical records when treatment is initiated.

Standard management includes physiotherapy and/or oral spasticity agents.

Authority required (STREAMLINED)

5408

Severe primary axillary hyperhidrosis

Clinical criteria:

Patient must have previously failed topical aluminium chloride hexahydrate after one to two months of treatment; OR

Patient must be intolerant to topical aluminium chloride hexahydrate treatment.

Population criteria:

Patient must be aged 12 years or older.

Treatment criteria:

Must be treated by a dermatologist; OR

Must be treated by a neurologist; OR

Must be treated by a paediatrician.

Maximum number of treatments per year is 3, with no less than 4 months to elapse between treatments.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

5409

Urinary incontinence

Clinical criteria:

The condition must be due to neurogenic detrusor overactivity, as demonstrated by urodynamic study, AND

The condition must be inadequately controlled by anti-cholinergic therapy, AND

Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with Botulinum Toxin Type A Neurotoxin Complex, AND

Patient must be willing and able to self-catheterise, AND

The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment, AND

Patient must have multiple sclerosis; OR

Patient must have a spinal cord injury; OR

Patient must be aged 18 years or older and have spina bifida.

Treatment criteria:

Must be treated by a urologist; OR

Must be treated by a urogynaecologist.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

5333

Urinary incontinence

Clinical criteria:

The condition must be due to idiopathic overactive bladder, AND

The condition must have been inadequately controlled by therapy involving at least two alternative anti-cholinergic agents, AND

Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with botulinum toxin type A neurotoxin complex, AND

Patient must be willing and able to self-catheterise, AND

The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a urologist; OR

Must be treated by a urogynaecologist.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

5262

Chronic migraine

Clinical criteria:

Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with botulinum toxin type A neurotoxin, AND

Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with botulinum toxin type A neurotoxin, AND

Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of headache days per month after two treatment cycles (each of 12 weeks duration) in order to be eligible for continuing PBS-subsidised treatment, AND

Patient must be appropriately managed by his or her practitioner for medication overuse headache, prior to initiation of treatment with botulinum toxin.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a neurologist.

Prophylactic migraine medications are propanolol, amitriptylin, methsergide, pizotifen, cyproheptadine or topiramate.

Note Special Pricing Arrangements apply.

botulinum toxin type A 100 units injection, 1 vial

6103F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	..	..	*1625.85	38.30	Botox [AG]

▪ CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)

5405
Blepharospasm or hemifacial spasm
Clinical criteria:
Patient must have blepharospasm; OR
Patient must have hemifacial spasm.
Population criteria:
Patient must be aged 18 years or older.
Treatment criteria:
Must be treated by a neurologist; OR
Must be treated by an ophthalmologist; OR
Must be treated by an otolaryngology head and neck surgeon; OR
Must be treated by a plastic surgeon.
Authority required (STREAMLINED)

5359
Dynamic equinus foot deformity
Clinical criteria:
The condition must be due to spasticity, AND
Patient must have cerebral palsy, AND
Patient must be ambulant.
Population criteria:
Patient must be aged from 2 to 17 years inclusive.
Treatment criteria:
Must be treated by a neurologist; OR
Must be treated by an orthopaedic surgeon; OR
Must be treated by a paediatrician; OR
Must be treated by a rehabilitation specialist.
Authority required (STREAMLINED)

5332
Dynamic equinus foot deformity
Clinical criteria:
The condition must be due to spasticity, AND
Patient must be an ambulant cerebral palsy patient, AND
Patient must have commenced on PBS-subsidised treatment with clostridium botulinum type A toxin-haemagglutinin complex as a paediatric patient.
Population criteria:
Patient must be aged 18 years or older.
Treatment criteria:
Must be treated by a neurologist; OR
Must be treated by an orthopaedic surgeon; OR
Must be treated by a paediatrician; OR
Must be treated by a rehabilitation specialist.
Authority required (STREAMLINED)

5220
Moderate to severe spasticity of the upper limb following a stroke
Clinical criteria:
The condition must be moderate to severe spasticity of the upper limb/s following stroke, defined as a Modified Ashworth Scale rating of 3 or more, AND
The treatment must not be initiated until three months post-stroke, AND
The treatment must only be used as second line therapy when standard management has failed; OR
The treatment must only be used as an adjunct to physical therapy, AND
The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (total Botox, Dysport, and Xeomin), AND
The treatment must not exceed 4 treatment periods (total Botox, Dysport, and Xeomin) per upper limb per lifetime, AND
Patient must not have established severe contracture in the limb to be treated.
Population criteria:
Patient must be aged 18 years or older.
Treatment criteria:
Must be treated by a neurologist; OR
Must be treated by an orthopaedic surgeon; OR
Must be treated by a rehabilitation specialist; OR
Must be treated by a plastic surgeon; OR
Must be treated by a geriatrician.
The date of the stroke must be documented in the patient's medical records when treatment is initiated.
Standard management includes physiotherapy and/or oral spasticity agents.
Authority required (STREAMLINED)

5406
Spasmodic torticollis
Clinical criteria:
Patient must have spasmodic torticollis, AND
The treatment must be as monotherapy; OR
The treatment must be as adjunctive therapy to current standard care.
Treatment criteria:
Must be treated by a neurologist; OR
Must be treated by a plastic surgeon; OR
Must be treated by a rehabilitation specialist.

clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial

1152P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	..	..	*1420.69	38.30	Dysport [IS]

clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial

6293F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*1272.07	38.30	Dysport [IS]

▪ INCOBOTULINUMTOXINA

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)
5360
Blepharospasm
Clinical criteria:
Patient must have blepharospasm; OR
Patient must have blepharospasm.
Population criteria:
Patient must be aged 18 years or older.
Treatment criteria:
Must be treated by a neurologist; OR
Must be treated by an ophthalmologist; OR
Must be treated by an otolaryngology head and neck surgeon; OR
Must be treated by a plastic surgeon.

Authority required (STREAMLINED)
5222
Spasmodic torticollis
Clinical criteria:
Patient must have spasmodic torticollis, AND
The treatment must be as monotherapy; OR
The treatment must be as adjunctive therapy to current standard care.
Population criteria:
Patient must be aged 18 years or older.
Treatment criteria:
Must be treated by a neurologist; OR
Must be treated by a plastic surgeon; OR
Must be treated by a rehabilitation specialist.

Authority required (STREAMLINED)
5220
Moderate to severe spasticity of the upper limb following a stroke
Clinical criteria:
The condition must be moderate to severe spasticity of the upper limb/s following stroke, defined as a Modified Ashworth Scale rating of 3 or more, AND
The treatment must not be initiated until three months post-stroke, AND
The treatment must only be used as second line therapy when standard management has failed; OR
The treatment must only be used as an adjunct to physical therapy, AND
The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (total Botox, Dysport, and Xeomin), AND
The treatment must not exceed 4 treatment periods (total Botox, Dysport, and Xeomin) per upper limb per lifetime, AND
Patient must not have established severe contracture in the limb to be treated.
Population criteria:
Patient must be aged 18 years or older.
Treatment criteria:
Must be treated by a neurologist; OR

Must be treated by an orthopaedic surgeon; OR
Must be treated by a rehabilitation specialist; OR
Must be treated by a plastic surgeon; OR
Must be treated by a geriatrician.
The date of the stroke must be documented in the patient's medical records when treatment is initiated.
Standard management includes physiotherapy and/or oral spasticity agents.

incobotulinumtoxinA 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial

10253P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4	..	..	*1546.93	38.30	Xeomin [EZ]

Growth Hormone Program

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES

Somatropin and somatropin agonists

SOMATROPIN

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Short stature and slow growth

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height below the 1st percentile for age and sex, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must not have a bone age of 2.5 years or less, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm, AND

Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; OR

Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation of the patient's maturational or constitutional delay status; AND

6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height below the 1st percentile for age and sex, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Initial treatment

Clinical criteria:

Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR

Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR

Patient must be female and menarche occurred before the chronological age of 10 years, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Confirmation that the patient has precocious puberty; AND

7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a structural lesion that is not neoplastic; OR

Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND

Patient must have hypothalamic obesity, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity above the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of greater than 8 cm per year, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

8. Confirmation that the patient has hypothalamic obesity; AND

9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height at or below the 95th percentile for age on the Turner syndrome growth curve for girls, AND

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must not have a bone age of 2.5 years or less, AND

Patient must not have a height greater than or equal to 155.0 cm, AND

Patient must not have a bone age of 13.5 years or greater.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height below the 1st percentile for age and sex, AND

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height at or below the 25th percentile for age and sex, AND

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2 ; AND

6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge

10518N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	223.15	38.30	Omnitrope Surepal 5 [SZ]

somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge

6476W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	223.15	38.30	Omnitrope [SZ]

somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge

10514J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	439.36	38.30	Omnitrope Surepal 10 [SZ]

somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge

6311E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	439.36	38.30	Omnitrope [SZ]

somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge

10446T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	655.58	38.30	Omnitrope Surepal 15 [SZ]

▪ SOMATROPIN

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Short stature and slow growth

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height below the 1st percentile for age and sex, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must not have a bone age of 2.5 years or less, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm, AND

Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; OR

Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation of the patient's maturational or constitutional delay status; AND

6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height below the 1st percentile for age and sex, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a chronological age of less than 2 years, AND

Patient must have a documented clinical risk of hypoglycaemia, AND

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Initial treatment

Clinical criteria:

Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR

Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR

Patient must be female and menarche occurred before the chronological age of 10 years, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Confirmation that the patient has precocious puberty; AND

7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a structural lesion that is not neoplastic; OR

Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND

Patient must have hypothalamic obesity, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity above the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of greater than 8 cm per year, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

8. Confirmation that the patient has hypothalamic obesity; AND

9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height at or below the 95th percentile for age on the Turner syndrome growth curve for girls, AND

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must not have a bone age of 2.5 years or less, AND

Patient must not have a height greater than or equal to 155.0cm, AND

Patient must not have a bone age of 13.5 years or greater.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height below the 1st percentile for age and sex, AND

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

SOMATROPIN (Recombinant human growth hormone) Injection 8 mg (24 i.u.) vial with 1.37 mL diluent cartridge (with preservative) (for use with one.click auto-injector), 1

6329D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	352.88	38.30	Saizen 8 mg click.easy [SG]

somatropin 12 units (4 mg) injection [1 vial] (&) inert substance diluent [1 vial], 1 pack

6266T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	179.90	38.30	Zomacton [FP]

somatropin 18 units (6 mg/1.03 mL) injection, 1.03 mL cartridge

5822K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	266.39	38.30	Saizen [SG]

somatropin 30 units (10 mg) injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack

6310D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	439.36	38.30	Zomacton [FP]

somatropin 36 units (12 mg/1.5 mL) injection, 1.5 mL cartridge

5824M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	525.85	38.30	Saizen [SG]

somatropin 60 units (20 mg/2.5 mL) injection, 2.5 mL cartridge

3388H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	871.79	38.30	Saizen [SG]

▪ SOMATROPIN

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Short stature and slow growth

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height below the 1st percentile for age and sex, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must not have a bone age of 2.5 years or less, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm, AND

Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; OR

Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation of the patient's maturational or constitutional delay status; AND

6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height below the 1st percentile for age and sex, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a chronological age of less than 2 years, AND

Patient must have a documented clinical risk of hypoglycaemia, AND

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Initial treatment

Clinical criteria:

Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR

Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR

Patient must be female and menarche occurred before the chronological age of 10 years, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Confirmation that the patient has precocious puberty; AND

7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a structural lesion that is not neoplastic; OR

Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND

Patient must have hypothalamic obesity, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity above the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of greater than 8 cm per year, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

8. Confirmation that the patient has hypothalamic obesity; AND

9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height at or below the 95th percentile for age on the Turner syndrome growth curve for girls, AND

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must not have a bone age of 2.5 years or less, AND

Patient must not have a height greater than or equal to 155.0cm, AND

Patient must not have a bone age of 13.5 years or greater.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height below the 1st percentile for age and sex, AND

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height at or below the 25th percentile for age and sex, AND

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2 ; AND

6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge

5818F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	223.15	38.30	Norditropin FlexPro [NO]

somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge

6295H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	223.15	38.30	Norditropin SimpleXx [NO]

somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge

5819G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	439.36	38.30	Norditropin FlexPro [NO]

somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge

6296J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	439.36	38.30	Norditropin SimpleXx [NO]

somatropin 30 units (10 mg/2 mL) injection, 2 mL cartridge

9604L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	439.36	38.30	NutropinAq [IS]

somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge

5820H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	655.58	38.30	Norditropin FlexPro [NO]

somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge

6297K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	655.58	38.30	Norditropin SimpleXx [NO]

▪ SOMATROPIN

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Short stature and slow growth

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height below the 1st percentile for age and sex, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must not have a bone age of 2.5 years or less, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm, AND

Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; OR

Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation of the patient's maturational or constitutional delay status; AND

6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height below the 1st percentile for age and sex, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a chronological age of less than 2 years, AND

Patient must have a documented clinical risk of hypoglycaemia, AND

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Initial treatment

Clinical criteria:

Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR

Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR

Patient must be female and menarche occurred before the chronological age of 10 years, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Confirmation that the patient has precocious puberty; AND

7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a structural lesion that is not neoplastic; OR

Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND

Patient must have hypothalamic obesity, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity above the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of greater than 8 cm per year, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

8. Confirmation that the patient has hypothalamic obesity; AND

9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height at or below the 95th percentile for age on the Turner syndrome growth curve for girls, AND

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must not have a bone age of 2.5 years or less, AND

Patient must not have a height greater than or equal to 155.0cm, AND

Patient must not have a bone age of 13.5 years or greater.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height below the 1st percentile for age and sex, AND

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height at or below the 25th percentile for age and sex, AND

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be prepubertal.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2 ; AND

6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

somatropin 18 units (6 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

6169Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	266.39	38.30	Humatrope [LY]

somatropin 36 units (12 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

6170R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	525.85	38.30	Humatrope [LY]

somatropin 72 units (24 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

6345Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	1044.77	38.30	Humatrope [LY]

▪ SOMATROPIN

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Short stature and slow growth

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height below the 1st percentile for age and sex, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must not have a bone age of 2.5 years or less, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm, AND

Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; OR

Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation of the patient's maturational or constitutional delay status; AND

6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height below the 1st percentile for age and sex, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a chronological age of less than 2 years, AND

Patient must have a documented clinical risk of hypoglycaemia, AND

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Initial treatment

Clinical criteria:

Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR

Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR

Patient must be female and menarche occurred before the chronological age of 10 years, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome ,

hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Confirmation that the patient has precocious puberty; AND

7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a structural lesion that is not neoplastic; OR

Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND

Patient must have hypothalamic obesity, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity above the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of greater than 8 cm per year, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

8. Confirmation that the patient has hypothalamic obesity; AND

9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height at or below the 95th percentile for age on the Turner syndrome growth curve for girls, AND

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must not have a bone age of 2.5 years or less, AND

Patient must not have a height greater than or equal to 155.0cm, AND

Patient must not have a bone age of 13.5 years or greater.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height below the 1st percentile for age and sex, AND

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height at or below the 25th percentile for age and sex, AND

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, AND

Patient must be male, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2 ; AND

6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); OR

Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist, AND

Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with no sleep disorders identified; OR

Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified which are not of sufficient severity to require treatment; OR

Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified for which the patient is currently receiving ameliorative treatment, AND

Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, AND

Patient must not have a chronological age of 18 years or greater.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. A minimum of 6 months of recent growth data (height, weight and waist circumference). The most recent data must not be older than three months; AND

4. The date that skeletal maturity was achieved (if applicable); AND

5. (a) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome; OR

(b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist

6. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months and any sleep disorders identified via polysomnography that required treatment have been addressed; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with 1 repeat allowed)

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1

9586M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	525.85	38.30	Genotropin GoQuick [PF]

SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1

9585L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	223.15	38.30	Genotropin GoQuick [PF]

somatropin 1.8 units (600 microgram) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

9628R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	188.56	38.30	Genotropin MiniQuick [PF]

somatropin 2.4 units (800 microgram) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

6313G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	249.09	38.30	Genotropin MiniQuick [PF]

somatropin 3 units (1 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

6314H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	309.63	38.30	Genotropin MiniQuick [PF]

somatropin 3.6 units (1.2 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

6315J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	370.17	38.30	Genotropin MiniQuick [PF]

somatropin 36 units (12 mg) injection [1 cartridge] (&) inert substance diluent [1 mL cartridge], 1 pack

6312F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	525.85	38.30	Genotropin [PF]

somatropin 4.2 units (1.4 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

6316K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	430.71	38.30	Genotropin MiniQuick [PF]

somatropin 4.8 units (1.6 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

6317L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	491.26	38.30	Genotropin MiniQuick [PF]

somatropin 5.4 units (1.8 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

6318M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	551.80	38.30	Genotropin MiniQuick [PF]

somatropin 6 units (2 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

6319N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	612.33	38.30	Genotropin MiniQuick [PF]

▪ SOMATROPIN

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Short stature and slow growth

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, AND

Patient must not have been on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a bone age of 13.5 years or greater, AND

Patient must not have a height greater than or equal to 155.0 cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, AND

Patient must not have been on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature and slow growth

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special

Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months;

OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND

4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); OR

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to

commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have a chronological age of less than 2 years, AND

Patient must have a documented clinical risk of hypoglycaemia, AND

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR

Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR

Patient must be female and menarche occurred before the chronological age of 10 years, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. Confirmation that the patient has precocious puberty; AND

4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have a structural lesion that is not neoplastic; OR

Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND

Patient must have hypothalamic obesity, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

9. A bone age result performed within the last 12 months; AND

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, AND

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a bone age of 2.5 years or less, AND

Patient must not have a bone age of 13.5 years or greater, AND

Patient must not have a height greater than or equal to 155.0 cm.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. A height measurement from immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

SOMATROPIN (Recombinant human growth hormone) Injection 8 mg (24 i.u.) vial with 1.37 mL diluent cartridge (with preservative) (for use with one.click auto-injector), 1

10433D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	352.88	38.30	Saizen 8 mg click.easy [SG]

somatropin 12 units (4 mg) injection [1 vial] (&) inert substance diluent [1 vial], 1 pack

10452D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	179.90	38.30	Zomacton [FP]

somatropin 18 units (6 mg/1.03 mL) injection, 1.03 mL cartridge

10462P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	266.39	38.30	Saizen [SG]

somatropin 30 units (10 mg) injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack

10440L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	439.36	38.30	Zomacton [FP]

somatropin 36 units (12 mg/1.5 mL) injection, 1.5 mL cartridge

10483R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	525.85	38.30	Saizen [SG]

somatropin 60 units (20 mg/2.5 mL) injection, 2.5 mL cartridge

10497L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	871.79	38.30	Saizen [SG]

▪ SOMATROPIN

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Short stature and slow growth

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a chronological age of 5 years or greater.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature and slow growth

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND

4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); OR

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have a chronological age of less than 2 years, AND

Patient must have a documented clinical risk of hypoglycaemia, AND

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR

Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR

Patient must be female and menarche occurred before the chronological age of 10 years, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. Confirmation that the patient has precocious puberty; AND

4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must have a structural lesion that is not neoplastic; OR

Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND

Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND

Patient must have hypothalamic obesity, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Recent growth data (height and weight, not older than three months); AND

9. A bone age result performed within the last 12 months; AND

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, AND

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a bone age of 2.5 years or less, AND

Patient must not have a height greater than or equal to 155.0 cm, AND

Patient must not have a bone age of 13.5 years or greater.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. A height measurement from immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

SOMATROPIN (Recombinant human growth hormone) Injection 8 mg (24 i.u.) vial with 1.37 mL diluent cartridge (with preservative) (for use with one.click auto-injector), 1

10471D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	352.88	38.30	Saizen 8 mg click.easy [SG]

somatropin 12 units (4 mg) injection [1 vial] (&) inert substance diluent [1 vial], 1 pack

10447W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	179.90	38.30	Zomacton [FP]

somatropin 18 units (6 mg/1.03 mL) injection, 1.03 mL cartridge

10458K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	266.39	38.30	Saizen [SG]

somatropin 30 units (10 mg) injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack

10455G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	439.36	38.30	Zomacton [FP]

somatropin 36 units (12 mg/1.5 mL) injection, 1.5 mL cartridge

10495J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	525.85	38.30	Saizen [SG]

somatropin 60 units (20 mg/2.5 mL) injection, 2.5 mL cartridge

10442N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	871.79	38.30	Saizen [SG]

▪ SOMATROPIN

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Short stature and slow growth

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

Population criteria:

Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to growth retardation secondary to an intracranial lesion, or cranial irradiation category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a chronological age of 5 years or greater.

Population criteria:

Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, AND

Patient must not have been on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a bone age of 13.5 years or greater, AND

Patient must not have a height greater than or equal to 155.0 cm.

Population criteria:

Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, AND

Patient must not have been on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, AND

Patient must not have been on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, AND

Patient must not have an eGFR equal to or greater than 30mL/min/1.73m2, AND

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m2 prescribers should seek reclassification to the indication short stature and slow growth.

Authority required

Short stature and slow growth

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to

commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months;

OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND

4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); OR

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a paediatric endocrinologist; OR

Must be treated by a medical practitioner in consultation with an endocrinologist specialising in paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR

Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR

Patient must be female and menarche occurred before the chronological age of 10 years, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. Confirmation that the patient has precocious puberty; AND

4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have a structural lesion that is not neoplastic; OR

Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND

Patient must have hypothalamic obesity, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

9. A bone age result performed within the last 12 months; AND

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, AND

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a bone age of 2.5 years or less, AND

Patient must not have a bone age of 13.5 years or greater, AND

Patient must not have a height greater than or equal to 155.0 cm.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. A height measurement from immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval

immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m2 ; AND

5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m2 prescribers should seek reclassification to the indication short stature and slow growth.

somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge

10427T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	223.15	38.30	Omnitrope [SZ]

somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge

10507B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	223.15	38.30	Omnitrope Surepal 5 [SZ]

somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge

10441M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	439.36	38.30	Omnitrope [SZ]

somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge

10506Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	439.36	38.30	Omnitrope Surepal 10 [SZ]

somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge

10490D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	655.58	38.30	Omnitrope Surepal 15 [SZ]

▪ SOMATROPIN

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Short stature and slow growth

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, AND

Patient must not have been on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a bone age of 13.5 years or greater, AND

Patient must not have a height greater than or equal to 155.0 cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, AND

Patient must not have been on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have been on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, AND

Patient must not have an eGFR equal to or greater than 30mL/min/1.73m2, AND

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m2 prescribers should seek reclassification to the indication short stature and slow growth.

Authority required

Short stature and slow growth

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to

commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months;

OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND

4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); OR

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have a chronological age of less than 2 years, AND

Patient must have a documented clinical risk of hypoglycaemia, AND

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR

Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR

Patient must be female and menarche occurred before the chronological age of 10 years, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. Confirmation that the patient has precocious puberty; AND

4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have a structural lesion that is not neoplastic; OR

Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND

Patient must have hypothalamic obesity, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

9. A bone age result performed within the last 12 months; AND

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, AND

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a bone age of 2.5 years or less, AND

Patient must not have a bone age of 13.5 years or greater, AND

Patient must not have a height greater than or equal to 155.0 cm.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. A height measurement from immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m2 ; AND

5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m2 prescribers should seek reclassification to the indication short stature and slow growth.

somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge

10432C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	223.15	38.30	Norditropin FlexPro [NO]

somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge

10469B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	223.15	38.30	Norditropin SimpleXx [NO]

somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge

10439K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	439.36	38.30	Norditropin SimpleXx [NO]

somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge

10451C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	439.36	38.30	Norditropin FlexPro [NO]

somatropin 30 units (10 mg/2 mL) injection, 2 mL cartridge

10478L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	439.36	38.30	NutropinAq [IS]

somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge

10449Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	655.58	38.30	Norditropin FlexPro [NO]

somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge

10468Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	655.58	38.30	Norditropin SimpleXx [NO]

▪ SOMATROPIN

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Short stature and slow growth

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, AND

Patient must not have been on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a bone age of 13.5 years or greater, AND

Patient must not have a height greater than or equal to 155.0 cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, AND

Patient must not have been on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, AND

Patient must not have been on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, AND

Patient must not have an eGFR equal to or greater than 30mL/min/1.73m2, AND

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be prepubertal.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m2 prescribers should seek reclassification to the indication short stature and slow growth.

Authority required

Short stature and slow growth

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months;

OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND

4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); OR

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have a chronological age of less than 2 years, AND

Patient must have a documented clinical risk of hypoglycaemia, AND

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR

Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR

Patient must be female and menarche occurred before the chronological age of 10 years, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. Confirmation that the patient has precocious puberty; AND

4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have a structural lesion that is not neoplastic; OR

Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND

Patient must have hypothalamic obesity, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

9. A bone age result performed within the last 12 months; AND

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, AND

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a bone age of 2.5 years or less, AND

Patient must not have a bone age of 13.5 years or greater, AND

Patient must not have a height greater than or equal to 155.0 cm.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. A height measurement from immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval

immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be prepubertal.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m2 ; AND

5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m2 prescribers should seek reclassification to the indication short stature and slow growth.

somatropin 18 units (6 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

10482Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	266.39	38.30	Humatrope [LY]

somatropin 36 units (12 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

10487Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	525.85	38.30	Humatrope [LY]

somatropin 72 units (24 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

10476J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	1044.77	38.30	Humatrope [LY]

▪ SOMATROPIN

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Short stature and slow growth

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a chronological age of 5 years or greater.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be female and must not have a height greater than or equal to 155.0cm.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, AND

Patient must not have an eGFR equal to or greater than 30mL/min/1.73m2, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2 ; AND

6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

If a patient receiving treatment under the indication 'short stature associated with chronic renal insufficiency' undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m2 prescribers should seek reclassification to the indication short stature and slow growth.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature and slow growth

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND

4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); OR

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to

commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate,

midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR

Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR

Patient must be female and menarche occurred before the chronological age of 10 years, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. Confirmation that the patient has precocious puberty; AND

4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have a structural lesion that is not neoplastic; OR

Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND

Patient must have hypothalamic obesity, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Recent growth data (height and weight, not older than three months); AND

9. A bone age result performed within the last 12 months; AND

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature asscciated with Turner syndrome, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, AND

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a bone age of 2.5 years or less, AND

Patient must not have a height greater than or equal to 155.0 cm, AND

Patient must not have a bone age of 13.5 years or greater.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. A height measurement from immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2 ; AND

5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m2 prescribers should seek reclassification to the indication short stature and slow growth.

somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge

10484T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	223.15	38.30	Omnitrope [SZ]

somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge

10512G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	223.15	38.30	Omnitrope Surepal 5 [SZ]

somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge

10481P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	439.36	38.30	Omnitrope [SZ]

somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge

10519P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	439.36	38.30	Omnitrope Surepal 10 [SZ]

somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge

10485W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	655.58	38.30	Omnitrope Surepal 15 [SZ]

▪ SOMATROPIN

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Short stature and slow growth

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a chronological age of 5 years or greater.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, AND

Patient must not have an eGFR equal to or greater than 30mL/min/1.73m2, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

Population criteria:

Patient must be prepubertal.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2 ; AND

6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

If a patient receiving treatment under the indication 'short stature associated with chronic renal insufficiency' undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m2 prescribers should seek reclassification to the indication short stature and slow growth.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature and slow growth

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND

4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); OR

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine,

glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have a chronological age of less than 2 years, AND

Patient must have a documented clinical risk of hypoglycaemia, AND

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR

Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR

Patient must be female and menarche occurred before the chronological age of 10 years, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. Confirmation that the patient has precocious puberty; AND

4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must have a structural lesion that is not neoplastic; OR

Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND

Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND

Patient must have hypothalamic obesity, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Recent growth data (height and weight, not older than three months); AND

9. A bone age result performed within the last 12 months; AND

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, AND

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a bone age of 2.5 years or less, AND

Patient must not have a height greater than or equal to 155.0 cm, AND

Patient must not have a bone age of 13.5 years or greater.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. A height measurement from immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be prepubertal.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2 ; AND

5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m2 prescribers should seek reclassification to the indication short stature and slow growth.

somatropin 18 units (6 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

10429X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	266.39	38.30	Humatrope [LY]

somatropin 36 units (12 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

10461N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	525.85	38.30	Humatrope [LY]

somatropin 72 units (24 mg) injection [1 cartridge] (&) inert substance diluent [3.15 mL syringe], 1 pack

10502R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	1044.77	38.30	Humatrope [LY]

▪ SOMATROPIN

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Short stature and slow growth

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a chronological age of 5 years or greater.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, AND

Patient must not have an eGFR equal to or greater than 30mL/min/1.73m2, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2 ; AND

6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

If a patient receiving treatment under the indication 'short stature associated with chronic renal insufficiency' undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m2 prescribers should seek reclassification to the indication short stature and slow growth.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature and slow growth

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program)

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND

4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); OR

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to

commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have a chronological age of less than 2 years, AND

Patient must have a documented clinical risk of hypoglycaemia, AND

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR

Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR

Patient must be female and menarche occurred before the chronological age of 10 years, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. Confirmation that the patient has precocious puberty; AND

4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must have a structural lesion that is not neoplastic; OR

Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND

Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND

Patient must have hypothalamic obesity, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6

months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Recent growth data (height and weight, not older than three months); AND

9. A bone age result performed within the last 12 months; AND

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, AND

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a bone age of 2.5 years or less, AND

Patient must not have a height greater than or equal to 155.0 cm, AND

Patient must not have a bone age of 13.5 years or greater.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. A height measurement from immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2 ; AND

5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m2 prescribers should seek reclassification to the indication short stature and slow growth.

somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge

10437H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	223.15	38.30	Norditropin SimpleXx [NO]

somatropin 15 units (5 mg/1.5 mL) injection, 1.5 mL cartridge

10467X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	223.15	38.30	Norditropin FlexPro [NO]

somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge

10448X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	439.36	38.30	Norditropin SimpleXx [NO]

somatropin 30 units (10 mg/1.5 mL) injection, 1.5 mL cartridge

10496K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	439.36	38.30	Norditropin FlexPro [NO]

somatropin 30 units (10 mg/2 mL) injection, 2 mL cartridge

10438J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	439.36	38.30	NutropinAq [IS]

somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge

10470C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	655.58	38.30	Norditropin SimpleXx [NO]

somatropin 45 units (15 mg/1.5 mL) injection, 1.5 mL cartridge

10489C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	655.58	38.30	Norditropin FlexPro [NO]

▪ SOMATROPIN

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Short stature and slow growth

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a chronological age of 5 years or greater.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program)

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, AND

Patient must not have an eGFR equal to or greater than 30mL/min/1.73m2, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2 ; AND

6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

If a patient receiving treatment under the indication 'short stature associated with chronic renal insufficiency' undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m2 prescribers should seek reclassification to the indication short stature and slow growth.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and poor body composition due to Prader Willi syndrome category, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have a current bone age below skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies); OR

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by a significant medical illness; OR

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have been re-evaluated via polysomnography for airway obstruction and apnoea during the initial 32 week treatment period and any sleep disorders identified that required treatment must have been addressed, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have developed uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height.

Population criteria:

Patient must not have a chronological age of equal to or greater than 18 years.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND

3. Recent growth data (height, weight, and waist circumference, not older than three months); AND

4. The date at which skeletal maturity was achieved (if applicable) [Note: A bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity.]; AND

5. Confirmation that during the initial 32 week treatment period, the patient was re-evaluated via polysomnography for airway obstruction and apnoea, and any sleep disorders that were identified have been addressed; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature and slow growth

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND

4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); OR

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have a chronological age of less than 2 years, AND

Patient must have a documented clinical risk of hypoglycaemia, AND

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR

Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR

Patient must be female and menarche occurred before the chronological age of 10 years, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program)

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. Confirmation that the patient has precocious puberty; AND

4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome ,

hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must have a structural lesion that is not neoplastic; OR

Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND

Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND

Patient must have hypothalamic obesity, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Recent growth data (height and weight, not older than three months); AND

9. A bone age result performed within the last 12 months; AND

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, AND

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a bone age of 2.5 years or less, AND

Patient must not have a height greater than or equal to 155.0 cm, AND

Patient must not have a bone age of 13.5 years or greater.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. A height measurement from immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

5. Recent growth data (height and weight, not older than three months); AND

6. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m2 ; AND

5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m2 prescribers should seek reclassification to the indication short stature and slow growth.

Authority required

Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and poor body composition due to Prader-Willi syndrome, AND

Patient must have had a lapse in growth hormone treatment, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have a current bone age below skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies) , unless response was affected by an adverse reaction to growth hormone; OR

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); OR

Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist, AND

Patient must have been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment and any sleep disorders identified that required treatment must have been addressed; OR

Patient must have been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment and any sleep disorders identified that required treatment must have been addressed; OR

Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with no sleep disorders identified; OR

Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with no sleep disorders identified; OR

Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified which are not of sufficient severity to require treatment; OR

Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified which are not of sufficient severity to require treatment; OR

Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified for which the patient is currently receiving ameliorative treatment; OR

Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified for which the patient is currently receiving ameliorative treatment, AND

Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a chronological age of 18 years or greater.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND

3. (a) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome, OR

(b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; AND

4. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment, and any sleep disorders identified via the polysomnography that required treatment have been addressed; AND

5. Recent growth data (height and weight, not older than three months); AND

6. The date that skeletal maturity was achieved (if applicable); AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10426R	1	1	..	525.85	38.30	Genotropin GoQuick [PF]

SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10435F	1	1	..	223.15	38.30	Genotropin GoQuick [PF]

somatropin 1.8 units (600 microgram) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10477K	1	1	..	188.56	38.30	Genotropin MiniQuick [PF]

somatropin 2.4 units (800 microgram) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10463Q	1	1	..	249.09	38.30	Genotropin MiniQuick [PF]

somatropin 3 units (1 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10430Y	1	1	..	309.63	38.30	Genotropin MiniQuick [PF]

somatropin 3.6 units (1.2 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10457J	1	1	..	370.17	38.30	Genotropin MiniQuick [PF]

somatropin 36 units (12 mg) injection [1 cartridge] (&) inert substance diluent [1 mL cartridge], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10444Q	1	1	..	525.85	38.30	Genotropin [PF]

somatropin 4.2 units (1.4 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10434E	1	1	..	430.71	38.30	Genotropin MiniQuick [PF]

somatropin 4.8 units (1.6 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10498M	1	1	..	491.26	38.30	Genotropin MiniQuick [PF]

somatropin 5.4 units (1.8 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10501Q	1	1	..	551.80	38.30	Genotropin MiniQuick [PF]

somatropin 6 units (2 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10472E	1	1	..	612.33	38.30	Genotropin MiniQuick [PF]

▪ SOMATROPIN

Authority required

Short stature and slow growth

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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HOBART TAS 7001

GH

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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HOBART TAS 7001

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
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Authority required

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, AND

Patient must not have been on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a bone age of 13.5 years or greater, AND

Patient must not have a height greater than or equal to 155.0 cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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HOBART TAS 7001

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, AND

Patient must not have been on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have been on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), AND

Patient must not have diabetes mellitus, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, AND

Patient must not have an eGFR equal to or greater than 30mL/min/1.73m2, AND

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m2 prescribers should seek reclassification to the indication short stature and slow growth.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and poor body composition due to Prader-Willi syndrome category, AND

Patient must have been re-evaluated via polysomnography for airway obstruction and apnoea during the initial 32 week treatment period and any sleep disorders identified that required treatment must have been addressed, AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must have maintained or improved height percentile for age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must have maintained or improved body mass index SDS for age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment

period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must have maintained or improved waist circumference while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must have maintained or improved waist/height ratio (waist circumference in centimetres divided by height in centimetres) while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must have achieved an increase in height percentile with reference to the untreated Prader-Willi syndrome standards for age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must not have been on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must have maintained or improved body mass index while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must have maintained or improved body mass index SDS for age and sex while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must have maintained or improved waist circumference while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must have maintained or improved waist/height ratio (waist circumference in centimetres divided by height in centimetres) while on the maximum dose of 0.04mg/kg/week for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must have maintained or improved weight SDS for age and sex while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), and have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females), AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have developed uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height.

Population criteria:

Patient must not have a chronological age of equal to or greater than 18 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height, weight and waist circumference) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. The date at which skeletal maturity was achieved (if applicable) [Note: A bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity.]; AND

5. Confirmation that during the initial 32 week treatment period, the patient was re-evaluated via polysomnography for airway obstruction and apnoea, and any sleep disorders that were identified have been addressed; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Maintenance is defined as a value within a 5% tolerance (this allows for seasonal and other measurement variations).

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Applications for authority to prescribe should be forwarded to:

Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Short stature and slow growth

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months;

OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND

4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

GH

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); OR

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
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HOBART TAS 7001

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have a chronological age of less than 2 years, AND

Patient must have a documented clinical risk of hypoglycaemia, AND

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND

4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR

Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR

Patient must be female and menarche occurred before the chronological age of 10 years, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. Confirmation that the patient has precocious puberty; AND

4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have a structural lesion that is not neoplastic; OR

Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome , hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone

deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, AND

Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), AND

Patient must have hypothalamic obesity, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

9. A bone age result performed within the last 12 months; AND

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, AND

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a bone age of 2.5 years or less, AND

Patient must not have a bone age of 13.5 years or greater, AND

Patient must not have a height greater than or equal to 155.0 cm.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. A height measurement from immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. A bone age result performed within the last 12 months; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth

hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment, AND

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m2 ; AND

5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m2 prescribers should seek reclassification to the indication short stature and slow growth.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Prior Written Approval of Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and poor body composition due to Prader-Willi syndrome, AND

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have a current bone age below skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies) , unless response was affected by an adverse reaction to growth hormone; OR

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, AND

Patient must have diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); OR

Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist, AND

Patient must have been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment and any sleep disorders identified that required treatment must have been addressed, AND

Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height, AND

Patient must not have diabetes mellitus, AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, AND

Patient must not have an active tumour or evidence of tumour growth or activity, AND

Patient must not have a chronological age of 18 years or greater.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special

Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome, OR

(b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; AND

4. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment, and any sleep disorders identified via the polysomnography that required treatment have been addressed; AND

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

6. The date that skeletal maturity was achieved (if applicable); AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1

10431B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	525.85	38.30	Genotropin GoQuick [PF]

SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1

10443P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	223.15	38.30	Genotropin GoQuick [PF]

somatropin 1.8 units (600 microgram) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

10456H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	188.56	38.30	Genotropin MiniQuick [PF]

somatropin 2.4 units (800 microgram) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

10479M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	249.09	38.30	Genotropin MiniQuick [PF]

somatropin 3 units (1 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

10480N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	309.63	38.30	Genotropin MiniQuick [PF]

somatropin 3.6 units (1.2 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

10453E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	370.17	38.30	Genotropin MiniQuick [PF]

somatropin 36 units (12 mg) injection [1 cartridge] (&) inert substance diluent [1 mL cartridge], 1 pack

10499N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	525.85	38.30	Genotropin [PF]

somatropin 4.2 units (1.4 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

10488B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	430.71	38.30	Genotropin MiniQuick [PF]

somatropin 4.8 units (1.6 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

10454F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	491.26	38.30	Genotropin MiniQuick [PF]

somatropin 5.4 units (1.8 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

10500P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	551.80	38.30	Genotropin MiniQuick [PF]

somatropin 6 units (2 mg) injection [7] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

10428W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	612.33	38.30	Genotropin MiniQuick [PF]

IVF Treatment Program

GENITO URINARY SYSTEM AND SEX HORMONES

SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

PROGESTOGENS

Pregnen (4) derivatives

PROGESTERONE

Authority required (STREAMLINED)

4997

Assisted Reproductive Technology

Clinical criteria:

The treatment must be for luteal phase support as part of an assisted reproductive technology (ART) treatment cycle for infertile women, AND

Patient must be receiving medical services as described in items 13200 or 13201 of the Medicare Benefits Schedule.

The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.

progesterone 100 mg pessary, 15

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9608Q	3	..	..	*156.33	38.30	Oripro [ON]

progesterone 100 mg pessary, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10116K	2	..	..	*104.77	38.30	Endometrin [FP]

progesterone 200 mg pessary, 15

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9609R	3	..	..	*171.72	38.30	Oripro [ON]

PROGESTERONE

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

5045

Assisted Reproductive Technology

Clinical criteria:

The treatment must be for luteal phase support as part of an assisted reproductive technology (ART) treatment cycle for infertile women, AND

Patient must be receiving medical services as described in items 13200 or 13201 of the Medicare Benefits Schedule.

The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.

progesterone 8% vaginal gel, 15 applications

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
6366C	2	..	..	*300.37	38.30	Crinone 8% [SG]

GONADOTROPINS AND OTHER OVULATION STIMULANTS

Gonadotropins

CHORIOGONADOTROPIN ALFA

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

5019

Assisted Reproductive Technology

Clinical criteria:

Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

choriogonadotropin alfa 250 microgram/0.5 mL injection, 0.5 mL cartridge

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
6182J	1	..	..	62.99	38.30	Ovidrel [SG]

choriogonadotropin alfa 250 microgram/0.5 mL injection, 0.5 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
9631X	1	..	..	62.99	38.30	Ovidrel [SG]

▪ CORIFOLLITROPIN ALFA

Authority required (STREAMLINED)

5009

Assisted Reproductive Technology

Clinical criteria:

The treatment must be for controlled ovarian stimulation, AND

Patient must have an antral follicle count of 20 or less, AND

Patient must be receiving medical services as described in items 13200, 13201, or 13202 of the Medicare Benefits Schedule, AND

Patient must be undergoing a gonadotrophin releasing antagonist cycle.

corifollitropin alfa 100 microgram/0.5 mL injection, 0.5 mL syringe

5816D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	433.48	38.30	Elonva [MK]

corifollitropin alfa 150 microgram/0.5 mL injection, 0.5 mL syringe

5817E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	707.38	38.30	Elonva [MK]

▪ FOLLITROPIN ALFA

Authority required (STREAMLINED)

5027

Assisted Reproductive Technology

Clinical criteria:

Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

follitropin alfa 300 units (21.84 microgram)/0.5 mL injection, 0.5 mL cartridge

6431L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*293.85	38.30	Gonal-f Pen [SG]

follitropin alfa 450 units (32.76 microgram)/0.75 mL injection, 0.75 mL cartridge

6432M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*437.31	38.30	Gonal-f Pen [SG]

follitropin alfa 900 units (65.52 microgram)/1.5 mL injection, 1.5 mL cartridge

6433N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	5	..	..	*2116.03	38.30	Gonal-f Pen [SG]

▪ FOLLITROPIN ALFA + LUTROPIN ALFA

Authority required (STREAMLINED)

5250

Stimulation of follicular development

Clinical criteria:

Patient must have severe LH deficiency, AND

Patient must be considered appropriate for treatment with the combination product after titration of FSH and LH after at least one cycle of treatment, AND

Patient must be receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

follitropin alfa 150 units + lutropin alfa 75 units [1 vial] (&) inert substance diluent [1 vial], 1 pack

10491E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	7	..	..	*1217.44	38.30	Pergoveris [SG]

▪ FOLLITROPIN BETA

Authority required (STREAMLINED)

5027

Assisted Reproductive Technology

Clinical criteria:

Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge

6335K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*303.33	38.30	Puregon 300 IU/0.36 mL [MK]

follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge

6336L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	4	..	..	*1159.25	38.30	Puregon 600 IU/0.72 mL [MK]

follitropin beta 900 units/1.08 mL injection, 1.08 mL cartridge

6464F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	5	..	..	*2113.88	38.30	Puregon 900 IU/1.08 mL [MK]

▪ GONADOTROPHIN CHORIONIC HUMAN

Authority required (STREAMLINED)

5027

Assisted Reproductive Technology

Clinical criteria:

Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

gonadotrophin chorionic human 1500 units injection [3 ampoules] (&) inert substance diluent [3 x 1 mL ampoules], 1 pack

6178E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	48.28	38.30	Pregnyl [MK]

gonadotrophin chorionic human 5000 units injection [1 ampoule] (&) inert substance diluent [1 mL ampoule], 1 pack

6181H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*30.95	32.12	Pregnyl [MK]

▪ GONADOTROPHIN-MENOPAUSAL HUMAN

Authority required (STREAMLINED)

5027

Assisted Reproductive Technology

Clinical criteria:

Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

gonadotrophin-menopausal human 1200 units injection [1 vial] (&) inert substance diluent [2 x 1 mL syringes], 1 pack

2038G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	4	..	..	*2171.65	38.30	Menopur 1200 [FP]

gonadotrophin-menopausal human 600 units injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack

2036E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	3	..	..	*835.56	38.30	Menopur 600 [FP]

▪ LUTROPIN ALFA

Authority required (STREAMLINED)

5251

Stimulation of follicular development

Clinical criteria:

Patient must have severe LH deficiency, AND

Patient must be receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

lutropin alfa 75 units injection [1 vial] (&) inert substance diluent [1 mL vial], 1 pack

10465T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	7	..	..	*722.19	38.30	Luveris [SG]

▪ SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

▪ PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

HYPOTHALAMIC HORMONES

Gonadotropin-releasing hormones

▪ NAFARELIN

Authority required (STREAMLINED)

5046

Assisted Reproductive Technology

Clinical criteria:

The treatment must be for prevention of premature luteinisation and ovulation, AND

Patient must be undergoing controlled ovarian stimulation, AND

Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

nafarelin 200 microgram/actuation nasal spray, 60 actuations

5815C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*216.39	38.30	Synarel [PF]

Anti-gonadotropin-releasing hormones

▪ CETRORELIX

Authority required (STREAMLINED)

5046

Assisted Reproductive Technology

Clinical criteria:

The treatment must be for prevention of premature luteinisation and ovulation, AND

Patient must be undergoing controlled ovarian stimulation, AND

Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

cetrorelix 250 microgram injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack

9599F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	10	..	..	*462.23	38.30	Cetrotide [SG]

▪ GANIRELIX

Authority required (STREAMLINED)

5046

Assisted Reproductive Technology

Clinical criteria:

The treatment must be for prevention of premature luteinisation and ovulation, AND

Patient must be undergoing controlled ovarian stimulation, AND

Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

ganirelix 250 microgram/0.5 mL injection, 0.5 mL syringe

9583J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	10	..	..	*462.23	38.30	Orgalutran [MK]

ganirelix 250 microgram/0.5 mL injection, 5 x 0.5 mL syringes

9584K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*462.25	38.30	Orgalutran [MK]

Opiate Dependence Treatment Program

ODT

NERVOUS SYSTEM

OTHER NERVOUS SYSTEM DRUGS

DRUGS USED IN ADDICTIVE DISORDERS

Drugs used in opioid dependence

BUPRENORPHINE

Note Treatment must be in accordance with the law of the relevant State or Territory.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Treatment of opiate dependence, including maintenance and detoxification (withdrawal), within a framework of medical, social and psychological treatment

buprenorphine 2 mg tablet, 7

6308B NP

Max.Qty Packs	Price ex manufacturer $	Brand Name and Manufacturer
1	9.98	Subutex [IR]

buprenorphine 400 microgram tablet, 7

6307Y NP

Max.Qty Packs	Price ex manufacturer $	Brand Name and Manufacturer
1	5.85	Subutex [IR]

buprenorphine 8 mg tablet, 7

6309C NP

Max.Qty Packs	Price ex manufacturer $	Brand Name and Manufacturer
1	28.60	Subutex [IR]

BUPRENORPHINE + NALOXONE

Caution Buprenorphine with naloxone soluble film and buprenorphine with naloxone sublingual tablet do not meet all the criteria for bioequivalence. Patients being switched between sublingual tablets and soluble films may therefore require a dosage adjustment.

Note Treatment must be in accordance with the law of the relevant State or Territory.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Treatment of opiate dependence within a framework of medical, social and psychological treatment

buprenorphine 2 mg + naloxone 500 microgram sublingual film, 28

9749D NP

Max.Qty Packs	Price ex manufacturer $	Brand Name and Manufacturer
1	46.20	Suboxone Film 2/0.5 [IR]

buprenorphine 8 mg + naloxone 2 mg sublingual film, 28

9750E NP

Max.Qty Packs	Price ex manufacturer $	Brand Name and Manufacturer
1	132.44	Suboxone Film 8/2 [IR]

METHADONE

Caution The risk of drug dependence is high.

Note Shared Care Model:
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Treatment of opiate dependence in accordance with the law of the relevant State or Territory

methadone hydrochloride 5 mg/mL oral liquid, 1 L

6172W NP

Max.Qty Packs	Price ex manufacturer $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	33.20	[a] Aspen Methadone Syrup [QA]	[a] Biodone Forte [MW]

methadone hydrochloride 5 mg/mL oral liquid, 200 mL

6171T NP

Max.Qty Packs	Price ex manufacturer $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	7.91	[a] Aspen Methadone Syrup [QA]	[a] Biodone Forte [MW]

Repatriation Pharmaceutical Benefits Scheme

BENEFICIARIES' ENTITLEMENT CARDS AND ELIGIBILITY FOR REPATRIATION PHARMACEUTICAL BENEFITS

Gold card
This card is issued to those veterans of Australia's defence force, their widows/widowers and dependants entitled to treatment for all medical conditions.

White card
A White Card is issued to Australian veterans or mariners under the Veterans' Entitlements Act 1986 with:

- an accepted war or service-caused injury or disease;
- malignant cancer (neoplasia) whether war-caused or not;
- pulmonary tuberculosis whether war-caused or not;
- post-traumatic stress disorder whether war-caused or not; or
- anxiety and/or depression whether war-caused or not.

Orange card
Orange Repatriation pharmaceutical benefits cards are issued to Commonwealth and allied veterans and mariners who:

- have qualifying service from World War I or II and
- are aged 70 or over and
- have been resident in Australia for 10 years or more.

For more information go to the Department of Veterans' Affairs website:
http://www.dva.gov.au

RPBS Explanatory Notes
Introduction

The Australian Repatriation System

- The Australian Repatriation system is based primarily on the principle of compensation to veterans and eligible dependants for injury or death related to war service. In certain cases, treatment is also provided for accepted injuries or conditions that are not service-related or have occurred as a result of other than war service.
- Through the *Veterans' Entitlements Act 1986* the Department of Veterans' Affairs provides programs of compensation, income support and treatment for eligible veterans and their dependants. One of the defined benefits for eligible veterans is the Repatriation Pharmaceutical Benefits Scheme. This range of medications and dressings is more comprehensive than is available through the Pharmaceutical Benefits Scheme.

RPBS prescribing provisions

- Unless otherwise stated, Repatriation Pharmaceutical Benefits Scheme (RPBS) prescriptions must conform with the requirements of Pharmaceutical Benefits Scheme (PBS) prescriptions, as detailed in Section 1 – Explanatory Notes in the *Schedule of Pharmaceutical Benefits* book. The prescriber shall ensure that a prescription contains the following details:
  - the category of benefit, i.e., RPBS, by placing a cross in the relevant box;
  - the patient's full name and address;
  - the prescription date;
  - the DVA file number of the patient as evidence of entitlement;
  - in the case of authority prescriptions, the Authority approval number or the four digit streamlined authority code;
  - the item, form, strength, quantity and directions;
  - the number of repeats, if applicable;
  - indicate when brand substitution is not permitted; and
  - the name, signature, the prescriber number and address of the prescriber.

Prior Approval Arrangements

- The prior approval of the Department is required to prescribe the following:
  - 'Authority required' items (excluding 'Authority required (STREAMLINED)' items) listed in either the PBS or RPBS Schedule;
  - increased quantities and/or repeats of items listed in either the PBS or RPBS Schedule;
  - items listed under section 100 of the *National Health Act 1953*; and
  - other items not listed in either Schedule (non-Schedule items).
- The above items are to be prescribed on the common PBS/RPBS authority prescription form in accordance with the directions stated in the Explanatory Notes in the *Schedule of Pharmaceutical Benefits* (See also information regarding dental prescribing and prescribing by optometrists under the RPBS in these Notes.)
- All Authority required prescriptions and requests for non-Schedule items must receive prior approval from the Department. This can be achieved by either:
  - using the Department's national free call number 1800 552 580; or
  - by mailing the written authority prescription to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) at the reply paid address shown at the end of these RPBS Explanatory Notes.

Prior approval is not required from DVA to prescribe an Authority required (STREAMLINED) item (except where increased quantities and/or repeats are required). Instead the authority prescription form must include a four digit streamlined authority code.

- Some requests for prior approval (including some non-Schedule items) need to be referred by VAPAC to the Repatriation Pharmaceutical Reference Committee for consideration. In such cases a VAPAC pharmacist will advise the prescriber to submit a request in writing that provides the following information:
  - A current clinical report on the patient's condition (such as age, co-morbidities, renal, liver failure) and clinical reports including pathology, biochemistry, diagnostic and other investigations if appropriate.
  - Details of past and current therapy for the condition. Include details of PBS, RPBS and non-Schedule items utilised, and the results of those therapies.
  - Details of the proposed treatment regimen. Include intended dose and duration of treatment and objective measures of response.
  - When the proposed use of the item is outside the TGA-approved indications for use in Australia, provide copies of articles from peer reviewed publications supporting the proposed treatment.
  - Signed, informed patient consent where the item is to be used for a non-TGA-approved indication.
  - For items without Australian marketing approval, a copy of the TGA Special Access Scheme approval to prescribe the drug.
- Requests for prior approval to prescribe a non-Schedule (PBS or RPBS) item that is of the same therapeutic class (ATC level 3) as an item that is listed on the Schedule, will not be approved unless unequivocal clinical evidence is presented to demonstrate that the requested item is essential for effective treatment of the nominated patient.
- A pharmacist should not supply an item prescribed on an RPBS Authority Prescription Form unless the form has been approved and stamped by VAPAC, or has been endorsed by the prescriber with a telephone Authority approval number provided by VAPAC. Medicare Australia will not accept RPBS Authority prescriptions that have not been approved by the Department of Veterans' Affairs for payment.

Palliative Care Drugs

- The following medications may be available, or made available in increased quantities or doses under prior approval arrangements for use only in the palliative care of terminal disease:
  - clonazepam

- cyclizine
- dexamethasone
- disodium pamidronate
- fentanyl
- glycopyrrolate
- hyoscine butylbromide
- hyoscine hydrobromide
- ketamine
- midazolam
- octreotide

- For further information telephone VAPAC on 1800 552 580.

Dental Prescribing

- Under Department of Veterans' Affairs arrangements, financial responsibility for pharmaceutical benefits prescribed by a Local Dental Officer (LDO) is limited to treatment to which holders of the following cards are entitled: Where possible the LDO shall prescribe in accordance with the provisions governing dental prescribing under the Pharmaceutical Benefits Scheme (PBS).
  - a Gold Repatriation Health Card – For All Conditions; or
  - a White Repatriation Health Card – For Specific Conditions; or
  - an Orange Repatriation Pharmaceutical Benefits Card.
- Prescriptions for PBS Dental Schedule items for Gold, White and Orange Card holders are to be dispensed at the PBS concessional rate. Claims for payment by the dispensing pharmacist are to be included with other Repatriation prescriptions. The card holder is required to meet the cost of any applicable brand premium.
- When a non-PBS Dental Schedule item is prescribed for an eligible card holder, the LDO's private prescription form should be used. The dispensing pharmacist may charge the patient the full cost of the prescription. The patient may claim a refund for the full cost of a non-Schedule item from the Department if an itemised receipt (not a cash register receipt) and a copy of the prescription are provided.

Prescribing by optometrists

- Optometrists approved as 'PBS prescribers' may write RPBS prescriptions as outlined in Section 1 for medicines listed in Section 2 of the PBS Schedule as pharmaceutical benefits for optometrical use.
- Medicines in the optometrist list include non-Authority and Authority required items. Procedures for obtaining VAPAC approval to prescribe 'Authority required' optometrist items or increased quantities and/or repeats of optometrist items under the RPBS are the same as indicated under prior approval arrangements above.
- The list of medicines for prescribing by optometrists under the RPBS is the same as applies under the PBS. There are no optometrist listings in the RPBS Schedule for prescribing for veterans only. There is no provision for optometrist prescribers to request approval to prescribe items that are not included in the PBS optometrist list (non-Schedule items).
- Optometrist PBS/RPBS prescription forms are for use for prescribing non-Authority or Authority required optometrist items under the RPBS with one item per form only.

Provisions governing pricing and payment for RPBS benefits

Introduction

- Unless otherwise stated, the pricing and payment principles and arrangements for approved pharmacists supplying pharmaceutical benefits under the RPBS will be the same as those arrangements applying under the PBS.
- Where a pharmaceutical benefit that is not listed on the PBS or RPBS Schedule is dispensed on an RPBS Authority prescription, a pharmacist will price the benefit and enter the serial number, prescription identifying number and price on the sticker or stamp imprint affixed to the prescription.

Pricing of Schedule Items

- Items supplied under the RPBS from the PBS Schedule, both ready-prepared and extemporaneously-prepared, will be paid on the same basis as benefits supplied under the PBS. Items supplied under the RPBS from the Repatriation Schedule, including wound dressings, will be paid on the basis of the price as given in the Repatriation Pharmaceutical Benefits section (Section 1 – RPBS Schedule, Drugs, Medicines and Dressings) of the *Schedule of Pharmaceutical Benefits*.

Pricing of Non-Schedule Ready Prepared Items

- Non-Schedule ready-prepared items are to be priced on the basis of the invoiced, GST-exclusive wholesale price to pharmacists plus the appropriate PBS mark-up and the PBS dispensing fee. Where the item price to pharmacists is greater than $100.00, a copy of the invoice pertaining to the supply of that item is to be submitted together with the appropriate copy of the authority prescription as part of the claim for payment.

Pricing of Non-Schedule Extemporaneously Prepared Items

- When an ingredient drug is not listed in the PBS Drug Tariff, the recovery price will be based on the invoiced wholesale price to pharmacists, increased by a mark-up of 100%, calculated in accordance with the directions contained in the pricing instructions for pricing of PBS extemporaneously-prepared benefits in this Schedule. The price paid by the pharmacist for the commercial pack from which the ingredient is used shall be endorsed on the prescription form.

Miscellaneous Pricing Rules

- The price to pharmacists used as the basis of pricing will be the invoiced, GST-exclusive price from the wholesaler.
- If multiple quantities of a manufacturer's original pack are supplied, the PBS mark-up is applied to the price to pharmacist of each pack and then totalled. The PBS dispensing fee, and the PBS dangerous drug fee if applicable, are then added to the total of the marked-up prices.

- When the quantity prescribed corresponds with the quantity of a manufacturer's original pack, in no circumstances will the price payable for one pack exceed that payable for multiples or combinations of packs to supply the quantity prescribed.
- The list of ingredient drugs and prices included in the PBS Drug Tariff are common to both the PBS and RPBS. Certain restrictions apply regarding the prescribing and dispensing of some of these ingredient drugs as pharmaceutical benefits, e.g., use as additive only.
- For items prescribed generically, including non-Schedule and wound dressings, the pharmacist should indicate on the prescription the quantity and brand supplied. If prescriptions are not endorsed, the Department will pay the lowest priced acceptable product available.

General

Packaging Material, Postage or Freight

- Payment to a pharmacist for the costs of packaging materials, postage or freight required to supply a pharmaceutical benefit is to be paid by the patient, who may then claim reimbursement from the Department through the provision of a pharmacists itemised receipt.

Payment for Items Supplied at Short Intervals

- For all items dispensed at specific short intervals of time, the Department will pay a separate PBS dispensing fee for each occasion that the drug is supplied and which is acknowledged on receipt by the patient or agent.
- The price payable on the items supplied will be based on the individual dose quantity supplied. Where applicable, a PBS dangerous drug fee and a minimum container charge will be payable for each supply.

Receipts for Patient Charges

- Where a charge is paid by a patient in any of the circumstances of paragraphs 13 or 24, the pharmacist is required to provide a printed receipt to the patient with the details of the items or services provided, the amount paid, date of supply and the patients name and address. The patient may apply for reimbursement from the Department.

Special Patient Contributions

- The Special Patient Contribution for items listed as Special Pharmaceutical Benefits in the PBS Schedule is not payable by veterans entitled to pharmaceutical benefits under the RPBS. Eligible veterans receiving Special Pharmaceutical Benefits under the RPBS are required to pay only the concessional patient contribution and any applicable brand premium. If a Safety Net Entitlement card is held, the veteran should receive a Special Pharmaceutical Benefit free of charge, subject to any brand premium applicable. Medicare Australia will reimburse the dispensing pharmacist the total dispensed price, less the concessional patient contribution and/or brand premium if applicable.

Therapeutic Group Premiums — Authority Processing

- Items attracting a therapeutic group premium are dual listed. Dispensing pharmacists are therefore required to select the appropriate code for those items that are dual listed as authority and non-authority items, in order to correctly charge the patient and claim from Medicare Australia. Those authority prescriptions that grant exemption from a therapeutic group premium will have the letters 'TPX' at the beginning of the telephone Authority approval number, or, in the case of a written approval, will be stamped with the words "This prescription does not attract a therapeutic group premium".

Contact the Department of Veterans' Affairs

Authority Prescription Applications

Applications for authority to prescribe under the Repatriation Pharmaceutical Benefits Scheme (RPBS) should be sent to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) using the free postal service:

REPLY PAID 9998
VAPAC (Veterans' Affairs Pharmaceutical Advisory Centre)
Department of Veterens' Affairs
GPO Box 9998
BRISBANE QLD 4001

For RPBS enquiries and telephone approvals 24 hours a day the Freecall number is: 1800 552 580
Departmental pharmacists answer applications for prior approval for non-Schedule items and Authority application calls.

Wound Assessment and Dressing Identification

It is essential to define the aetiology of the wound before selecting a dressing. Recommendations are based on wound type, colour of wound base, depth of wound, and amount of exudate.
This wound chart adheres to the MOIST WOUND concept of healing and wound dressings are described below as ABSORBING or MOISTURE DONATING.
Most wound healing products are designed to remain in situ for several days, with the exception of those for infected wounds which should be changed daily. The quantities and repeats listed in the Repatriation Schedule are considered to be adequate to manage the treatment of a wound for two weeks to one month, when an assessment of the wound's healing process should be undertaken.

DRESSINGS

Pink Epithelialising Wound

Aim: To protect and promote epithelialisation. Epithelialising wounds normally are superficial and only produce a light exudate.

(A) Covering	• Film; • Film Island	• Gauze—Paraffin; • Non-adherent
(B) Absorbing	• Foam (Light Exudate); • Hydroactive (Superficial Wound—Light Exudate)	• Hydrocolloid (Superficial Wound—Light Exudate)

Red Granulating Wound

Aims: (1) to protect the granulating tissue; (2) to encourage epithelialisation; (3) to absorb excess exudate.

LIGHT EXUDATE:	Superficial	Cavity
(A) Absorbing	• Foam (Light Exudate); • Hydroactive (Superficial Wound—Light Exudate); • Hydrocolloid (Superficial Wound—Light Exudate)	• Hydrocolloid (Cavity Wound)
(B) Moisture donating	• Hydrogel—Amorphous; • Hydrogel—Sheet	• Hydrogel—Amorphous
HIGH EXUDATE:	Superficial	Cavity
(A) Absorbing	• Alginate (Superficial Wound); • Foam—Heavy Exudate; • Hydroactive (Superficial Wound—Moderate Exudate); • Hydrocolloid (Superficial Wound—Moderate/High Exudate)	• Alginate (Cavity Wound); • Foam—Moderate Exudate (see “cavity conforming” product); • Hydroactive (Cavity Wound); • Hydrocolloid (Cavity Wound)
(B) Moisture donating	NOT APPROPRIATE	

Yellow Sloughy Wound

Aims: (1) to remove slough; (2) to encourage granulation; (3) to absorb excess exudate.

LIGHT EXUDATE:	Superficial	Cavity
(A) Absorbing	• Cadexomer Iodine; • Foam—Light Exudate; • Foam with Charcoal; • Hydroactive (Superficial Wound—Moderate Exudate); • Hydrocolloid (Superficial Wound—Moderate Exudate)	• Cadexomer Iodine; • Hydrocolloid (Cavity Wound)
(B) Moisture Donating	• Hydrogel—Amorphous; • Hydrogel—Sheet	• Hydrogel—Amorphous
HIGH EXUDATE:	Superficial	Cavity
(A) Absorbing	• Alginate (Superficial Wound); • Cadexomer Iodine; • Foam—Heavy Exudate; • Hydroactive (Superficial Wound—Moderate/High Exudate); • Hydrocolloid (Superficial Wound—Moderate/High Exudate)	• Alginate (Cavity Wound); • Cadexomer Iodine; • Hydrocolloid (Cavity Wound)
(B) Moisture donating	NOT APPROPRIATE	

Black Necrotic Wound
Aims: To remove eschar by — (1) sharp debridement, e.g., scissor/scalpel and/or (2) rehydration and autolytic debridement. (These wounds usually produce a LIGHT EXUDATE.)

DRY / LIGHT EXUDATE:	Superficial	Cavity
(A) Absorbing	• Hydroactive (Superficial Wound—Light Exudate); • Hydrocolloid (Superficial Wound—Light/Moderate Exudate)	• Hydrocolloid (Cavity Wound)
(B) Moisture donating	• Hydrogel—Amorphous; • Hydrogel—Sheet	• Hydrogel—Amorphous; • Hydrogel—Sheet

Infected Wounds
Aims: (1) to clear the infection with systemic antibiotics; (2) to absorb excess exudate; (3) to remove slough if present; (4) to decrease bacterial burden - by applying a Silver dressing or Cadexomer Iodine dressing.

Malodorous Wounds
Aims: (1) to clear infection if present; (2) to remove slough if present; (3) to clear colonising odour-producing bacteria **in** slough — by applying metronidazole gel, a Silver dressing or a Cadexomer Iodine dressing; (4) to absorb excess exudate.
Products: Activated Charcoal; Alginate with Charcoal; Foam with Charcoal; Silver dressing; Cadexomer Iodine dressing.

Minor Skin Trauma
Aims: (1) to stop bleeding; (2) to prevent infection; (3) to minimise the surface defect; (4) to promote epithelialisation.

Ordering Products

Ordering Coloplast Products
Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy, and ready supply has only been secured with Independence Australia on 1300 788 855. Please note that Coloplast are unable to guarantee ready supply or rebate for price differences on purchases outside this distributor.

Ordering Hartmann Products
Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

Ordering Molnlycke Healthcare Products
Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

Ordering Smith & Nephew Products
Smith & Nephew products are distributed via the three major wholesalers, API, SIGMA & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

RPBS

RPBS

RPBS

ALIMENTARY TRACT AND METABOLISM

STOMATOLOGICAL PREPARATIONS

STOMATOLOGICAL PREPARATIONS

Antiinfectives and antiseptics for local oral treatment

CHLORHEXIDINE

chlorhexidine gluconate 0.2% mouthwash, 250 mL

4161B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	15.18	6.20	Plaqacide [OB]

chlorhexidine gluconate 0.2% mouthwash, 300 mL

4204G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	18.12	6.20	Savacol Mouth and Throat Rinse [OM]

DRUGS FOR ACID RELATED DISORDERS

ANTACIDS

Calcium compounds

CALCIUM CARBONATE + GLYCINE

Note For patients with chronic renal failure.

calcium carbonate 420 mg + glycine 180 mg tablet: chewable, 100

4055K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*25.01	6.20	Titralac [MM]

Combinations and complexes of aluminium, calcium and magnesium compounds

ALUMINIUM HYDROXIDE WITH MAGNESIUM HYDROXIDE AND SIMETHICONE

ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE and SIMETHICONE Oral suspension 400 mg-400 mg-30 mg per 5 mL, 500 mL, 1

4118R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*24.53	6.20	Mylanta Double Strength [JT]

ALUMINIUM HYDROXIDE with MAGNESIUM HYDROXIDE and SIMETHICONE Tablet 400 mg-400 mg-40 mg, 100

4453J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	5	..	*45.63	6.20	Mylanta Double Strength [JT]

DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS

Synthetic anticholinergics, esters with tertiary amino group

MEBEVERINE

mebeverine hydrochloride 135 mg tablet, 90

4328T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	28.24	6.20	[a] Colese [AF]
			..	32.74	6.20	[a] Colofac [GO]

BELLADONNA AND DERIVATIVES, PLAIN

Belladonna alkaloids, semisynthetic, quaternary ammonium compounds

HYOSCINE BUTYLBROMIDE

hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules

4279F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	25.12	6.20	Buscopan [BY]

DRUGS FOR CONSTIPATION

DRUGS FOR CONSTIPATION

Softeners, emollients

▪ DOCUSATE

docusate sodium 50 mg tablet, 100

4200C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	17.28	6.20	Coloxyl 50 [FM]

Contact laxatives

▪ BISACODYL

bisacodyl 10 mg suppository, 10

10578R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	3	5	..	*23.04	6.20	[a] Petrus Bisacodyl Suppositories [PP]
			..	*24.33	6.20	[a] Dulcolax [BY]

bisacodyl 10 mg suppository, 12

10580W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	3	4	..	*20.76	6.20	Petrus Bisacodyl Suppositories [PP]

▪ DOCUSATE + SENNOSIDE B

docusate sodium 50 mg + sennoside B 8 mg tablet, 100

4028B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	17.37	6.20	Soflax [GN]

docusate sodium 50 mg + sennoside B 8 mg tablet, 90

10177P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	16.26	6.20	Pharmacy Action Laxative with Senna [GQ]

▪ DOCUSATE + SENNOSIDES

docusate sodium 50 mg + sennosides 11.27 mg tablet, 90

4198Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	16.30	6.20	[a] Chemists' Own Laxative with Senna [RW]	[a] Colaxsen [QA]
						[a] Co-Senna [PP]	
			..	19.35	6.20	[a] Coloxyl with Senna [FM]	

▪ SENNOSIDE B

sennoside B 7.5 mg tablet, 100

4455L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	15.79	6.20	[a] Senna-Gen [PP]
			..	16.89	6.20	[a] Senokot [RC]

Bulk-forming laxatives

▪ ISPAGHULA HUSK DRY

ispaghula husk dry 3.5 g oral liquid: powder for, 30 sachets

4285M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	20.18	6.20	Fybogel [RC]

▪ PSYLLIUM HUSK POWDER

PSYLLIUM HYDROPHILIC MUCILLOID Oral powder (non-flavoured) 336 g, 1

4422R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	20.51	6.20	Fibre Health Natural Granular [PP]
			..	23.68	6.20	Metamucil Natural Granular [PY]

PSYLLIUM HYDROPHILIC MUCILLOID Oral powder (orange-flavoured, sugar-free) 283 g, 1

4419N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	23.68	6.20	Metamucil Orange Smooth [PY]

▪ RHAMNUS FRANGULA + STERCULIA

rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g

4558X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	26.90	6.20	Normacol Plus [NE]

Enemas

▪ SORBITOL + CITRIC ACID + LAURYL SULFOACETATE SODIUM

sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 4 x 5 mL

4462W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	..	..	15.36	6.20	Micolette [AE]	Microlax [JT]

Other drugs for constipation

▪ GLYCEROL

glycerol 1.4 g suppository, 12

10596Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	3	5	..	*22.65	6.20	Petrus Pharmaceuticals Pty Ltd [PP]

glycerol 2.8 g suppository, 12

4246L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	3	5	..	*23.13	6.20	Petrus Pharmaceuticals Pty Ltd [PP]

glycerol 700 mg suppository, 12

10586E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	3	5	..	*22.29	6.20	Petrus Pharmaceuticals Pty Ltd [PP]

▪ ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS

ELECTROLYTES WITH CARBOHYDRATES

Oral rehydration salt formulations

▪ SODIUM CHLORIDE + POTASSIUM CHLORIDE + GLUCOSE MONOHYDRATE + CITRIC ACID

sodium chloride 470 mg + potassium chloride 300 mg + glucose monohydrate 3.56 g + sodium acid citrate 530 mg oral liquid: powder for, 10 x 4.9 g sachets

10574M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	16.06	6.20	restore O.R.S. [EA]

ANTIPROPULSIVES

Antipropulsives

▪ LOPERAMIDE

loperamide hydrochloride 2 mg capsule, 12

10592L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	11.91	6.20	Gastrex [CR]

▪ ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS

ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS

Peripherally acting antiobesity products

▪ ORLISTAT

Note The patient should be ideally enrolled in an exercise program and be receiving supplemental vitamins.

Authority required

Obesity

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a Body Mass Index (BMI) greater than or equal to 35 with no known co-morbidities; OR

Patient must have a BMI greater than or equal to 30 with 1 or more of the following co-morbidities;(i) diabetes;(ii) ischaemic heart disease;(iii) psychiatric conditions;(iv) hypertension, AND

Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available), AND

The treatment must not exceed 12 months in total from initial application, AND
Patient must not receive more than 1 continuous treatment in a lifetime.
The prescriber must provide the patient's initial body weight and BMI at the time of application.

Authority required

Obesity
Treatment Phase: Continuing treatment (3 to 6 months following commencement)
Clinical criteria:
Patient must have previously been issued with an authority prescription for this drug, AND
Patient must have reduced their inital body weight by 2.5 kg or 2.5% (whichever is the lesser) during the period 3 to 6 months following commencement of treatment with this drug, AND
The treatment must not exceed 12 months in total from initial application, AND
Patient must not receive more than 1 continuous treatment in a lifetime, AND
Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available).

Authority required

Obesity
Treatment Phase: Continuing treatment (6 to 12 months following commencement)
Clinical criteria:
Patient must have previously been issued with an authority prescription for this drug, AND
Patient must have reduced their inital body weight by 5 kg or 5% (whichever is the lesser) during the period 6 to 12 months following commencement of treatment with this drug, AND
The treatment must not exceed 12 months in total from initial application, AND
Patient must not receive more than 1 continuous treatment in a lifetime, AND
Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available).

orlistat 120 mg capsule, 84

4570M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	132.00	6.20	Xenical [RO]

▪ VITAMINS

VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12

Vitamin B1, plain

▪ THIAMINE

thiamine hydrochloride 100 mg tablet, 100

4043T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	2	..	13.47	6.20	Betavit [PP]

VITAMIN B-COMPLEX, INCL. COMBINATIONS

Vitamin B-complex, plain

▪ FERRIC PYROPHOSPHATE + THIAMINE + PYRIDOXINE + CYANOCOBALAMIN + LYSINE

cyanocobalamin 25 microgram/10 mL + iron (as ferric pyrophosphate) 10 mg/10 mL + lysine hydrochloride 300 mg/10 mL + pyridoxine hydrochloride 5 mg/10 mL + thiamine hydrochloride 10 mg/10 mL oral liquid, 200 mL

4493L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	16.44	6.20	Accomin Adult Tonic [PF]

▪ MINERAL SUPPLEMENTS

CALCIUM

Calcium

▪ CALCIUM

Restricted benefit

Hyperphosphataemia
Clinical criteria:
The condition must be associated with chronic renal failure.

CALCIUM Tablet (chewable) 500 mg (as carbonate), 60

4094L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	1	..	*28.97	6.20	[a] Cal-500 [PP]	[a] Cal-Sup [IA]

RPBS

CALCIUM Tablet 600 mg (as carbonate), 120

4142B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	1	..	*23.47	6.20	CAL-600 [PP]

▪ CALCIUM

Restricted benefit
Hypocalcaemia
Restricted benefit
Osteoporosis
Restricted benefit
Proven calcium malabsorption

CALCIUM Tablet (chewable) 500 mg (as carbonate), 60

4333C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*19.71	6.20	[a] Cal-500 [PP]	[a] Cal-Sup [IA]

CALCIUM Tablet 600 mg (as carbonate), 120

4082W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	16.94	6.20	CAL-600 [PP]

OTHER MINERAL SUPPLEMENTS

Magnesium

▪ MAGNESIUM ASPARTATE DIHYDRATE

Restricted benefit
Hypomagnesaemia
The condition must be documented in the patient's medical records.

magnesium aspartate dihydrate 500 mg (equivalent to 37.4 mg of magnesium) tablet, 50

4321K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	16.75	6.20	Mag-Sup [PP]
			..	17.35	6.20	Magmin [BB]

▪ BLOOD AND BLOOD FORMING ORGANS

▪ ANTITHROMBOTIC AGENTS

ANTITHROMBOTIC AGENTS

Platelet aggregation inhibitors excl. heparin

▪ ASPIRIN

aspirin 100 mg tablet, 112

10590J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	11.68	6.20	Spren 100 [QA]

aspirin 100 mg tablet, 90

4076M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	18.46	6.20	Cardiprin 100 [RC]

▪ ASPIRIN

Note The enteric coated preparations are for patients with a significant risk of gastrointestinal bleeding.

aspirin 100 mg capsule: enteric, 84

4078P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	17.55	6.20	Astrix [YN]

aspirin 100 mg tablet: enteric, 84

4077N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	16.76	6.20	Cardasa [AF] [a] Cartia [AS]	[a] Pharmacy Action Low Dose Aspirin [GQ]

▪ CLOPIDOGREL

Note Pharmaceutical benefits that have the forms clopidogrel tablet 75 mg (as besilate) and clopidogrel tablet 75 mg (as hydrogen sulfate) are equivalent for the purposes of substitution.

Authority required

For use in patients pre- and post-angioplasty

clopidogrel 75 mg tablet, 28

10169F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	..	16.38	6.20	[a] Clopidogrel GH [GQ]

clopidogrel 75 mg tablet, 28

4179Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	3	..	16.38	6.20	[a] APO-Clopidogrel [TX] [a] Clopidogrel AN [EA] [a] Piax [AF] [a] Terry White Chemists Clopidogrel [TW]	[a] Chem mart Clopidogrel [CH] [a] Iscover [AV] [a] Plavix [SW]

ANTIANEMIC PREPARATIONS

IRON PREPARATIONS

Iron bivalent, oral preparations

FERROUS FUMARATE

ferrous fumarate 200 mg (equivalent to 65.7 mg of elemental iron) tablet, 60

10594N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	14.94	6.20	Ferro-tab [AE]

Iron in combination with folic acid

FERROUS FUMARATE + FOLIC ACID

ferrous fumarate 310 mg (equivalent to 100 mg elemental iron) + folic acid 350 microgram tablet, 60

10579T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	15.96	6.20	Ferro-f-tab [AE]

VITAMIN B12 AND FOLIC ACID

Vitamin B12 (cyanocobalamin and analogues)

HYDROXOCOBALAMIN

Note One injection of hydroxocobalamin 1 mg every three months provides appropriate maintenance therapy in vitamin B12 deficiencies.

Note Pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as acetate) in 1 mL and pharmaceutical benefits that have the form hydroxocobalamin injection 1 mg (as chloride) in 1 mL are equivalent for the purposes of substitution.

Restricted benefit

Pernicious anaemia

Restricted benefit

Proven vitamin B12 deficiencies other than pernicious anaemia

Restricted benefit

Anaemias associated with vitamin B12 deficiency

Clinical criteria:

Patient must have had a gastrectomy, AND

The treatment must be for prophylaxis.

hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules

10577Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	14.69	6.20	[a] Vita-B12 [GH]

hydroxocobalamin 1 mg/mL injection, 3 x 1 mL ampoules

10587F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	14.69	6.20	[a] Neo-B12 [HH]

Folic acid and derivatives

FOLIC ACID

folic acid 500 microgram tablet, 100

10584C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	..	..	*14.49	6.20	[a] Foltabs 500 [PP]	[a] Megafol 0.5 [AF]

FOLIC ACID

Note The 5 mg strength tablet should be used in malabsorption states only.

folic acid 5 mg tablet, 100

10573L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	1	..	*16.71	6.20	Megafol 5 [AF]

BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS

IRRIGATING SOLUTIONS

Salt solutions

SODIUM CHLORIDE

sodium chloride 0.9% (4.5 g/500 mL) solution, 500 mL bottle

4460R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	13.82	6.20	Baxter Healthcare Pty Ltd [BX]

sodium chloride 0.9% (9 g/L) solution, 1 L bottle

4461T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	14.10	6.20	Baxter Healthcare Pty Ltd [BX]

CARDIOVASCULAR SYSTEM

VASOPROTECTIVES

AGENTS FOR TREATMENT OF HEMORRHOIDS AND ANAL FISSURES FOR TOPICAL USE

Other agents for treatment of hemorrhoids and anal fissures for topical use

ZINC OXIDE + PERU BALSAM + BENZYL BENZOATE

zinc oxide 10.75% + peru balsam 1.88% + benzyl benzoate 1.25% ointment, 50 g

4039N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	17.39	6.20	Anusol [JT]

zinc oxide 300 mg + peru balsam 50 mg + benzyl benzoate 33 mg suppository, 12

4040P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	16.45	6.20	Anusol [JT]

DERMATOLOGICALS

ANTIFUNGALS FOR DERMATOLOGICAL USE

ANTIFUNGALS FOR TOPICAL USE

Antibiotics

NYSTATIN

nystatin 100 000 units/g cream, 15 g

4001N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	15.43	6.20	Mycostatin [FM]

Imidazole and triazole derivatives

CLOTRIMAZOLE

clotrimazole 1% cream, 20 g

4004R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	12.18	6.20	[a] Pharmacy Action Anti-Fungal Cream [GQ]
			..	12.52	6.20	[a] Clonea [AF]

KETOCONAZOLE

Restricted benefit
Severe seborrhoeic dermatitis

ketoconazole 2% shampoo, 100 mL

4007X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	21.68	6.20	Sebizole [GN]

RPBS

ketoconazole 2% shampoo, 60 mL

4008Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	20.25	6.20	Nizoral 2% [JT]

▪ MICONAZOLE

miconazole 2% solution, 30 mL

4341L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	21.20	6.20	Daktarin Tincture [JT]

miconazole nitrate 2% cream, 30 g

4454K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	17.33	6.20	Daktarin [JT]

miconazole nitrate 2% cream, 40 g

3400Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	16.73	6.20	Resolve Thrush [EO]

Other antifungals for topical use

▪ AMOROLFINE

Restricted benefit

Onychomycosis

amorolfine 5% application, 5 mL

4010C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	67.06	6.20	[a] Pharmacy Action Anti-Fungal Nail Treatment [GQ]
			..	83.23	6.20	[a] Aporyl [TX]
			..	91.98	6.20	[a] Loceryl [GA]

▪ CICLOPIROX

Restricted benefit

Severe seborrhoeic dermatitis

ciclopirox olamine 1.5% shampoo, 60 mL

4106D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	21.13	6.20	Stieprox Liquid [GK]

▪ TERBINAFINE

Restricted benefit

Tinea pedis

terbinafine 1% gel, 15 g

4463X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	25.14	6.20	Lamisil DermGel [NC]

terbinafine hydrochloride 1% cream, 15 g

4473K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	1	..	23.87	6.20	[a] Lamisil [NC]	[a] Pharmacy Action Pharmisil [GQ]

▪ TOLNAFTATE

tolnaftate 0.07% spray, 100 g

4481W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	17.96	6.20	Tinaderm [BN]

ANTIFUNGALS FOR SYSTEMIC USE

Antifungals for systemic use

▪ TERBINAFINE

Authority required

Onychomycosis due to dermatophyte infection proven by microscopy or culture and confirmed by an approved pathology provider

terbinafine 250 mg tablet, 42

4011D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	34.20	6.20	[a] GenRx Terbinafine [GX]	[a] Lamisil (Novartis Pharmaceuticals Australia Pty Limited) [NV]
						[a] Tamsil [RW]	[a] Terbinafine GH [GQ]
						[a] Terbinafine Sandoz [SZ]	[a] Tinasil [AF]

▪ EMOLLIENTS AND PROTECTIVES

EMOLLIENTS AND PROTECTIVES

Silicone products

▪ DIMETHICONE-350 + GLYCEROL

Restricted benefit
For colostomy and ileostomy use
Restricted benefit
For use by paraplegic and quadriplegic patients
Restricted benefit
For use with surgical appliances

dimethicone-350 15% + glycerol 2% cream, 500 g

4551M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	27.80	6.20	Silic 15 [EO]

dimethicone-350 15% + glycerol 2% cream, 75 g

4556T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	15.73	6.20	Silic 15 [EO]

Soft paraffin and fat products

▪ WOOL ALCOHOLS

wool alcohols 6% ointment, 100 g

4041Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	17.17	6.20	Eucerin [BE]

Carbamide products

▪ UREA

urea 10% cream, 100 g

4042R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	15.44	6.20	Aquacare H.P. [AG]
			..	15.66	6.20	Urederm [IA]
			..	15.94	6.20	Calmurid [OL]

Other emollients and protectives

▪ CARMELLOSE SODIUM + GELATIN + PECTIN

carmellose sodium 16.7% + gelatin 16.7% + pectin 16.7% paste: oromucosal, 5 g

4518T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	15.14	6.20	Orabase [QA]

▪ SKIN EMOLLIENT

SKIN EMOLLIENT Bath oil 500 mL, 1

4122Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	19.92	6.20	Alpha Keri Bath Oil [MT]
			..	22.02	6.20	QV Bath Oil [EO]
			..	22.10	6.20	Hamilton Skin Therapy Oil [KY]

SKIN EMOLLIENT Lotion 500 mL, 1

4107E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	19.92	6.20	Alpha Keri Lotion [MT]

PROTECTIVES AGAINST UV-RADIATION

Protectives against UV-radiation for topical use

▪ SUNSCREENS

SUNSCREENS Cream 75 g, 1

4307Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	20.53	6.20	Sunsense Sensitive SPF 50+ [EO]

SUNSCREENS Lotion (non-alcoholic) 125 mL, 1

4546G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	18.73	6.20	Aquasun Lotion SPF 18 [PF]
			..	20.53	6.20	Sunsense Ultra SPF 50+ [EO]

▪ ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.

Anesthetics for topical use

▪ LIGNOCAINE

lignocaine hydrochloride anhydrous 2% oral liquid, 200 mL

4308R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	94.93	6.20	Xylocaine Viscous [AP]

Other antipruritics

▪ PINE TAR WITH TRIETHANOLAMINE LAURYL SULFATE

Note For patients who have failed to respond to simple moisturising agents.

PINE TAR with TRIETHANOLAMINE LAURYL SULFATE Solution 23 mg-60 mg per mL (2.3%-6%), 500 mL, 1

4408B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	24.77	6.20	Pinetarsol [EO]

▪ ANTIPSORIATICS

ANTIPSORIATICS FOR TOPICAL USE

Tars

▪ COAL TAR SOLUTION + PHENOL + SULFUR-PRECIPITATED

coal tar solution 5% + phenol 0.5% + sulfur-precipitated 0.5% gel, 30 g

4505D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	18.77	6.20	Egopsoryl-TA [EO]

▪ ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE

ANTIBIOTICS FOR TOPICAL USE

Other antibiotics for topical use

▪ MUPIROCIN

Restricted benefit

For the topical treatment of secondarily infected traumatic skin lesions

mupirocin 2% cream, 15 g

4348W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	19.84	6.20	Bactroban [GK]

mupirocin 2% ointment, 15 g

4350Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	19.84	6.20	Bactroban [GK]

CHEMOTHERAPEUTICS FOR TOPICAL USE

Antivirals

▪ PODOPHYLLOTOXIN

Authority required

For the treatment of ano-genital warts

podophyllotoxin 0.15% cream, 5 g

4390C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	52.16	6.20	Wartec Cream [GK]

Other chemotherapeutics

▪ INGENOL MEBUTATE

Authority required

Solar keratosis

Clinical criteria:

Patient must require topical drug therapy on the face and scalp as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

ingenol mebutate 0.015% gel, 3 x 470 mg

2464Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	138.23	6.20	Picato [LO]

▪ INGENOL MEBUTATE

Authority required

Solar (actinic) keratosis

Clinical criteria:

Patient must require topical drug therapy as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

ingenol mebutate 0.05% gel, 2 x 470 mg

2468X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	138.23	6.20	Picato [LO]

▪ CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS

CORTICOSTEROIDS, PLAIN

Corticosteroids, potent (group III)

▪ BETAMETHASONE VALERATE

betamethasone (as valerate) 0.1% cream, 30 g

4131K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	24.34	6.20	Betnovate [QA]

betamethasone (as valerate) 0.1% ointment, 30 g

4132L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	24.34	6.20	Betnovate [QA]

▪ MOMETASONE

Note Application to large areas of skin for longer than four weeks is not recommended.

mometasone furoate 0.1% cream, 50 g

4342M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	33.95	6.20	Elocon [MK]

mometasone furoate 0.1% ointment, 50 g

4343N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	33.95	6.20	Elocon [MK]

RPBS

▪ ANTISEPTICS AND DISINFECTANTS

ANTISEPTICS AND DISINFECTANTS

Iodine products

▪ POVIDONE-IODINE

povidone-iodine 10% solution, 100 mL

4411E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	24.06	6.20	Betadine Antiseptic Liquid [SW]

OTHER DERMATOLOGICAL PREPARATIONS

OTHER DERMATOLOGICAL PREPARATIONS

Medicated shampoos

COAL TAR SOLUTION + TAR + SALICYLIC ACID

coal tar solution 1% + tar 1% + salicylic acid 2% solution, 250 mL

4447C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	21.22	6.20	Sebitar [EO]

SALICYLIC ACID + BENZALKONIUM CHLORIDE + ALCOHOL + COAL TAR SOLUTION + POLYOXYETHYLENE ETHERS

SALICYLIC ACID with COAL TAR SOLUTION Scalp cleanser 20 mg-50 mg per mL (2%-5%), 200 mL, 1

4560B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	22.56	6.20	Ionil-T [GA]

SELENIUM SULFIDE

selenium sulfide 2.5% shampoo, 125 mL

4452H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	17.13	6.20	Selsun [DQ]

TAR + CADE OIL + COAL TAR + ARACHIS OIL EXTRACT OF COAL TAR

tar 0.3% (300 microgram/mL) + cade oil 0.03% (300 microgram/mL) + coal tar 0.01% (100 microgram/mL) + arachis oil extract of coal tar 0.3% (3 mg/mL) lotion, 300 mL

4405W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	25.83	6.20	Polytar [GK]

Wart and anti-corn preparations

SALICYLIC ACID + LACTIC ACID

salicylic acid 16.7% + lactic acid 16.7% application, 15 mL

4386W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	20.62	6.20	Duofilm Solution [GK]

Other dermatologicals

DICLOFENAC

Note Maximum quantity of four tubes (original + 3 repeats) in 12 months.

Authority required

Solar (actinic) keratosis

Treatment Phase: Management

Clinical criteria:

Patient must require topical drug therapy as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

diclofenac sodium 3% gel, 25 g

4046Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	3	..	57.48	6.20	Solaraze 3% Gel [CS]

ICHTHAMMOL

Note For patients who have failed to respond to simple moisturising agents.

ichthammol Cream 5 mg-10 mg-10 mg per g (0.5%-1%-1%), 50 g, 1

4281H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	20.58	6.20	Egoderm Cream [EO]

ICHTHAMMOL + ZINC OXIDE

Note For patients who have failed to respond to simple moisturising agents.

ichthammol 1% + zinc oxide 15% ointment, 50 g

4280G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	20.58	6.20	Egoderm Ointment [EO]

▪ IMIQUIMOD

Authority required

Superficial basal cell carcinoma
Treatment Phase: Primary treatment
Clinical criteria:
The condition must be confirmed by a histological diagnosis, AND
The condition must be one where other standard treatments are inappropriate, AND
The condition must require topical drug therapy.

imiquimod 5% cream, 12 x 250 mg sachets

4559Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	99.78	6.20	[a] Aldiq [QA]	[a] APO-Imiquimod [TX]
			..	102.47	6.20	[a] Aldara [IA]	

▪ IMIQUIMOD

Note Pharmaceutical benefits that have the form imiquimod single use sachets and pharmaceutical benefits that have the form imiquimod multi-use pump are equivalent for the purposes of substitution.

Authority required

Solar keratosis
Clinical criteria:
Patient must require topical drug therapy on the face and scalp as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

imiquimod 5% cream, 12 x 250 mg sachets

4134N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	99.78	6.20	[a] Aldiq [QA]	[a] APO-Imiquimod [TX]
			..	102.47	6.20	[a] Aldara [IA]	

imiquimod 5% cream, 2 x 2 g

10106X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	105.16	6.20	[a] Aldara Pump [IA]

▪ PANTHENOL

Note To be used in conjunction with the scalp cleanser salicylic acid with coal tar solution and pine tar (code 4447C).

panthenol conditioner, 200 g

4510J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	17.23	6.20	SebiRinse [EO]

▪ PARAFFIN LIGHT LIQUID + COCOAMPHODIACETATE DISODIUM

paraffin light liquid 3.5% + cocoamphodiacetate disodium 3% lotion, 500 mL

4549K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	22.87	6.20	Hamilton Skin Therapy Wash [KY]

▪ ZINC OXIDE + MAIZE STARCH + CHLORPHENESIN + TALC-PURIFIED

zinc oxide 25% + maize starch 55.85% + chlorphenesin 1% + talc-purified 18.07% powder: dusting, 100 g

4497Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	15.49	6.20	Z.S.C. [RW]

▪ GENITO URINARY SYSTEM AND SEX HORMONES

▪ GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS

ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS

Antibiotics

▪ NYSTATIN

nystatin 20 000 units/g vaginal cream, 75 g

4013F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	16.83	6.20	Nilstat [QA]

Imidazole derivatives

▪ CLOTRIMAZOLE

clotrimazole 1% cream, 35 g

4016J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	16.74	6.20	[a] Pharmacy Action FemCream [GQ]
			..	17.95	6.20	[a] APO-Clotrimazole 6 Day Cream [TX]

clotrimazole 2% cream, 20 g

4017K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	..	..	17.95	6.20	APO-Clotrimazole 3 Day Cream [TX]	Clonea 3 Day Cream [AF]

▪ OTHER GYNECOLOGICALS

OTHER GYNECOLOGICALS

▪ ACETIC ACID + HYDROXYQUINOLINE + RICINOLEIC ACID

acetic acid 0.94% + hydroxyquinoline sulfate 0.025% + ricinoleic acid 0.75% vaginal gel, 100 g

4434J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	33.45	6.20	Aci-Jel [CU]

▪ UROLOGICALS

UROLOGICALS

Drugs used in erectile dysfunction

▪ ALPROSTADIL

Authority required

Erectile dysfunction
Clinical criteria:
The condition must be vasculogenic; OR
The condition must be psychogenic; OR
The condition must be neurogenic, AND
Patient must have a specific accepted war-caused or service-related disability.
Population criteria:
Patient must be male.
Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

alprostadil 10 microgram injection [2] (&) inert substance diluent [2 x 0.6 mL syringes], 1 pack

4579B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	3	3	..	*100.47	6.20	Caverject Impulse [PF]

alprostadil 20 microgram injection [2] (&) inert substance diluent [2 x 0.6 mL syringes], 1 pack

4580C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	3	3	..	*125.31	6.20	Caverject Impulse [PF]

▪ SILDENAFIL

Authority required

Erectile dysfunction
Clinical criteria:
The condition must be vasculogenic; OR
The condition must be psychogenic; OR
The condition must be neurogenic, AND
Patient must have a specific accepted war-caused or service-related disability.
Population criteria:
Patient must be male.
Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

sildenafil 100 mg tablet, 4

4586J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	70.94	6.20	[a] APO-Sildenafil [TX]	[a] Chem mart Sildenafil [CH]
						[a] Sildenafil Actavis [UA]	[a] Sildenafil generichealth [GQ]
						[a] Terry White Chemists Sildenafil [TW]	[a] Vasafil 100 [QA]
						[a] Vedafil [AF]	
			..	82.47	6.20	[a] Silaran [RA]	[a] Viagra [PF]

RPBS

sildenafil 25 mg tablet, 4

4584G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	54.37	6.20	[a] Sildenafil Actavis [UA] [a] Vedafil [AF]	[a] Vasafil 25 [QA]
			..	54.38	6.20	[a] APO-Sildenafil [TX]	
			..	62.75	6.20	[a] Viagra [PF]	

sildenafil 50 mg tablet, 4

4585H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	66.37	6.20	[a] APO-Sildenafil [TX] [a] Vasafil 50 [QA]	[a] Sildenafil Actavis [UA] [a] Vedafil [AF]
			..	77.03	6.20	[a] Viagra [PF]	

▪ TADALAFIL

Authority required

Erectile dysfunction

Clinical criteria:

The condition must be vasculogenic; OR

The condition must be psychogenic; OR

The condition must be neurogenic, AND

Patient must have a specific accepted war-caused or service-related disability.

Population criteria:

Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

tadalafil 10 mg tablet, 4

4596X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	97.60	6.20	Cialis [LY]

tadalafil 20 mg tablet, 4

4597Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	97.60	6.20	Cialis [LY]

▪ VARDENAFIL

Authority required

Erectile dysfunction

Clinical criteria:

The condition must be vasculogenic; OR

The condition must be psychogenic; OR

The condition must be neurogenic, AND

Patient must have a specific accepted war-caused or service-related disability.

Population criteria:

Patient must be male.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

vardenafil 10 mg tablet, 4

4290T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	70.76	6.20	Levitra [BN]

vardenafil 20 mg tablet, 4

4302K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	80.51	6.20	Levitra [BN]

Other urologicals

▪ BICARBONATE + CITRIC ACID + TARTARIC ACID

Restricted benefit

Urinary symptoms

Clinical criteria:

The treatment must be for when antibiotic or other therapy alone is inappropriate.

sodium bicarbonate 1.76 g + citrate sodium 630 mg + citric acid 720 mg + tartaric acid 890 mg oral liquid: powder for, 28 x 4 g sachets

4049D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	‡1	4	..	16.62	6.20	Uracol [GN]	Ural Sachets [QA]

DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY

Alpha-adrenoreceptor antagonists

▪ ALFUZOSIN

Authority required

Benign prostatic hyperplasia

Clinical criteria:

Patient must be one in whom surgery is inappropriate; OR

Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

alfuzosin hydrochloride 10 mg tablet: modified release, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4277D	1	5	..	62.18	6.20	Xatral SR [SW]

▪ DUTASTERIDE + TAMSULOSIN

Authority required

Benign prostatic hyperplasia

Clinical criteria:

Patient must be one in whom surgery is inappropriate; OR

Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

dutasteride 500 microgram + tamsulosin hydrochloride 400 microgram capsule: modified release, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10102Q	1	5	..	34.47	6.20	Duodart 500ug/400ug [GK]

▪ TAMSULOSIN

Authority required

Benign prostatic hyperplasia

Clinical criteria:

Patient must be one in whom surgery is inappropriate; OR

Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

tamsulosin hydrochloride 400 microgram tablet: modified release, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
4070F	1	5	..	62.18	6.20	Flomaxtra [LS]	Tamsulosin Sandoz SR [SZ]

▪ TERAZOSIN

Authority required

Benign prostatic hyperplasia

Clinical criteria:

Patient must be one in whom surgery is inappropriate; OR

Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

terazosin 1 mg tablet [7 tablets] (&) terazosin 2 mg tablet [7 tablets], 14

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4396J	‡1	..	..	22.27	6.20	Hytrin [GO]

terazosin 10 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4399M	1	5	..	82.82	6.20	Hytrin [GO]

terazosin 2 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4397K	1	5	..	41.19	6.20	Hytrin [GO]

terazosin 5 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4398L	1	5	..	57.48	6.20	Hytrin [GO]

Testosterone-5-alpha reductase inhibitors

▪ DUTASTERIDE

Authority required

Benign prostatic hyperplasia

Clinical criteria:

Patient must be one in whom surgery is inappropriate; OR

Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

dutasteride 500 microgram capsule, 30

10095H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	..	30.26	6.20	Avodart [GK]

▪ FINASTERIDE

Authority required

Benign prostatic hyperplasia
Clinical criteria:
Patient must be one in whom surgery is inappropriate; OR
Patient must have failed to respond to other drug treatment or other drug treatment must be contraindicated.

finasteride 5 mg tablet, 28

4303L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	87.55	6.20	[a] Finpro [RZ]	[a] Pharmacy Choice Finasteride [RI]

finasteride 5 mg tablet, 30

4233T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	75.21	6.20	[a] Finasteride AN [EA]	[a] Finasteride GH 5 [GQ]
						[a] Finide [AL]	
			..	93.06	6.20	[a] Finasteride RBX [RA]	[a] Finnacar [RW]
			..	97.41	6.20	[a] APO-Finasteride [TX]	[a] Finasta [SZ]
						[a] Finasteride Alphapharm [AF]	[a] Finasteride-GA 5 [GN]
						[a] Pharmacor Finasteride 5 [CR]	[a] Proscar [MK]

▪ ANTIINFECTIVES FOR SYSTEMIC USE

▪ ANTIBACTERIALS FOR SYSTEMIC USE

MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

Macrolides

▪ AZITHROMYCIN

Restricted benefit

Upper and lower respiratory tract infections

azithromycin 500 mg tablet, 3

4115N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	32.24	6.20	Zedd 500 [RW]	
						[a] APO-Azithromycin [TX]	[a] Azithromycin-GA [UA]
						[a] Azithromycin Sandoz [SZ]	[a] Chem mart Azithromycin [CH]
						[a] Terry White Chemists Azithromycin [TW]	[a] Zithromax [PF]
						[a] Zitrocin [GN]	

▪ ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

▪ ANTINEOPLASTIC AGENTS

ANTIMETABOLITES

Pyrimidine analogues

▪ FLUOROURACIL

fluorouracil 5% cream, 20 g

4222F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	64.61	6.20	Efudix [IA]

▪ IMMUNOSUPPRESSANTS

IMMUNOSUPPRESSANTS

Tumor necrosis factor alpha (TNF-) inhibitors

▪ INFLIXIMAB

Note Any queries concerning the arrangements to prescribe infliximab may be directed to the Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC) on 1800 552 580.
Written applications for authority to prescribe infliximab should be forwarded to:
Reply Paid 9998
Veterans' Affairs Pharmaceutical Advisory Centre (VAPAC)
Department of Veterans' Affairs

GPO Box 9998
BRISBANE QLD 4001

Authority required

Initial treatment, in combination with methotrexate, of specific accepted war-caused or service-related disability of refractory rheumatoid arthritis. Initial treatment may be prescribed by rheumatologists or consultant physicians for the reduction of signs and symptoms and prevention of structural joint damage in adult patients with active rheumatoid arthritis who satisfy all of the following criteria:

(1) (a) Proven raised erythrocyte sedimentation rate (ESR) and/or C-reactive protein (CRP); and

(1) (b) Proven erosive rheumatoid arthritis without end-stage disease;

(2) Failure of an adequate trial of methotrexate and 2 other disease modifying anti-rheumatic drugs (such as sulfasalazine, hydroxychloroquine, leflunomide or cyclosporin) — unless these drugs were contraindicated or intolerance had developed;

(3) No history of active tuberculosis requiring treatment in the last 3 years;

(4) No history of opportunistic infection in the last 2 months;

(5) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form)

Authority required

Continuing treatment, in combination with methotrexate, of specific accepted war-caused or service-related disability of refractory rheumatoid arthritis. Continuing treatment may be prescribed by rheumatologists or consultant physicians, following initial therapy of 3 doses, in patients who satisfy the following criteria:

(1) There is improvement in ESR and/or CRP; and

(2) An ACR20 (American College of Rheumatology) response is achieved by 14 weeks after the commencement of therapy.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Infliximab (Remicade) RPBS Authority Application - Supporting Information form (contact the VAPAC on 1800 552 580 for a copy of the form)

infliximab 100 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4284L	1	2	..	671.48	6.20	Remicade [JC]

▪ MUSCULO-SKELETAL SYSTEM

▪ ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS

Acetic acid derivatives and related substances

▪ DICLOFENAC + MISOPROSTOL

Authority required

Patients requiring an NSAID in whom a risk of upper gastrointestinal complications is high or with a history of peptic ulcer disease

diclofenac sodium 50 mg + misoprostol 200 microgram tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4190M	1	2	..	37.69	6.20	Arthrotec 50 [PF]

▪ TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN

Preparations with salicylic acid derivatives

▪ EUCALYPTUS OIL + MENTHOL + METHYL SALICYLATE

eucalyptus oil 10% + menthol 4% + methyl salicylate 25% cream, 100 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4022Q	‡1	1	..	17.03	6.20	Gold Cross [BI]

▪ METHYL SALICYLATE

methyl salicylate 25% liniment, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4026X	‡1	1	..	13.48	6.20	Gold Cross [BI]

methyl salicylate 50% ointment, 100 g

4023R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	15.42	6.20	Gold Cross [BI]

▪ DRUGS FOR TREATMENT OF BONE DISEASES

DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

Bisphosphonates

▪ RISEDRONATE

Authority required

Preservation of bone mineral density

Clinical criteria:

Patient must be on long-term glucocorticoid therapy, AND

Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, AND

Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

RISEDRONATE SODIUM Tablet 35 mg (enteric coated), 4

2191H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	37.73	6.20	Actonel EC [UA]

risedronate sodium 35 mg tablet, 4

4444X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	37.73	6.20	[a] Acris Once-a-Week [AF]	[a] APO-Risedronate [TX]
					[a] Risedronate AN [EA]	[a] Risedronate-GA [GN]
					[a] Risedronate Sandoz [SZ]	[a] Risedro once a week [RW]

risedronate sodium 5 mg tablet, 28

4443W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	37.73	6.20	Actonel [UA]

Bisphosphonates, combinations

▪ ALENDRONATE + COLECALCIFEROL

Authority required

Preservation of bone mineral density

Clinical criteria:

Patient must be on long-term glucocorticoid therapy, AND

Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, AND

Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

alendronate 70 mg + colecalciferol 140 microgram tablet, 4

2224C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	39.35	6.20	[a] Alendronate plus D3-DRLA [RZ]	[a] FonatPlus [AF]
		..	41.84	6.20	[a] Fosamax Plus 70 mg/140 mcg [MK]	

alendronate 70 mg + colecalciferol 70 microgram tablet, 4

2194L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	39.35	6.20	[a] Alendronate plus D3-DRLA [RZ]	[a] FonatPlus [AF]
		..	41.85	6.20	[a] Fosamax Plus [MK]	

▪ ALENDRONATE + COLECALCIFEROL (&) CALCIUM CARBONATE

Authority required

Preservation of bone mineral density

Clinical criteria:

Patient must be on long-term glucocorticoid therapy, AND

Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, AND

Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

alendronate 70 mg + colecalciferol 140 microgram tablet [4] (&) calcium (as carbonate) 500 mg tablet [48], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2273P	‡1	5	..	42.49	6.20	Fosamax Plus D-Cal [MK]

▪ RISEDRONATE (&) CALCIUM CARBONATE

Authority required

Preservation of bone mineral density

Clinical criteria:

Patient must be on long-term glucocorticoid therapy, AND

Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, AND

Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

RISEDRONATE SODIUM and CALCIUM CARBONATE Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium), 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2220W	‡1	5	..	44.89	6.20	Actonel EC Combi [UA]

risedronate sodium 35 mg tablet [4] (&) calcium (as carbonate) 500 mg tablet [24], 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4059P	‡1	5	..	44.89	6.20	Acris Combi [AF]

▪ RISEDRONATE (&) CALCIUM CARBONATE + COLECALCIFEROL

Authority required

Preservation of bone mineral density

Clinical criteria:

Patient must be on long-term glucocorticoid therapy, AND

Patient must be undergoing continuous treatment with a dose equal to or greater than 7.5 mg of prednisone or equivalent per day, AND

Patient must be osteopenic (bone mineral density t-score of less than -1.0).

Prescribers need to demonstrate that the patient has been on continuous therapy for 3 months or more.

RISEDRONATE SODIUM and CALCIUM CARBONATE with COLECALCIFEROL Pack containing 4 enteric coated tablets risedronate sodium 35 mg and 24 sachets containing granules of calcium carbonate 2.5 g (equivalent to 1 g calcium) with colecalciferol 22 micrograms, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2254P	‡1	5	..	44.89	6.20	Actonel EC Combi D [UA]

▪ NERVOUS SYSTEM

▪ ANALGESICS

OPIOIDS

Natural opium alkaloids

▪ MORPHINE

Caution The risk of drug dependence is high.

Note Authorities for increased maximum quantities and/or repeats will be granted only for:
(i) chronic severe disabling pain associated with proven malignant neoplasia; or
(ii) chronic severe disabling pain where treatment has been initiated by a specialist with appropriate expertise in pain management.

Restricted benefit

Chronic severe disabling pain

Clinical criteria:

The condition must be unresponsive to non-opioid analgesics.

morphine sulfate 200 mg tablet: modified release, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4349X	1	..	..	115.81	6.20	MS Contin [MF]

OTHER ANALGESICS AND ANTIPYRETICS

Salicylic acid and derivatives

▪ ASPIRIN + CODEINE

aspirin 300 mg + codeine phosphate 8 mg tablet: dispersible, 40

4286N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	17.17	6.20	Aspalgin 40 [QA]

Anilides

▪ PARACETAMOL

paracetamol 240 mg/5 mL oral liquid, 200 mL

10599W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	14.12	6.20	Panamax 240 Elixir [SW]

paracetamol 500 mg tablet, 100

10582Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	12.07	6.20	[a] APO-Paracetamol [TX] [a] Generic Health Pty Ltd [GQ] [a] Paracetamol (Sandoz) [SZ] [a] Parapane [AF]	[a] Febridol [EA] [a] Panamax [SW] [a] Paralgin [FM]

▪ PARACETAMOL

Restricted benefit

Persistent pain

Clinical criteria:

The condition must be associated with osteoarthritis.

paracetamol 665 mg tablet: modified release, 96

10598T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*17.89	6.20	Osteomol 665 Paracetamol [CR]

▪ PARACETAMOL

Restricted benefit

Chronic arthropathies

paracetamol 500 mg tablet, 100

10585D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	4	..	*15.36	6.20	[a] APO-Paracetamol [TX] [a] Generic Health Pty Ltd [GQ] [a] Paracetamol (Sandoz) [SZ] [a] Parapane [AF]	[a] Febridol [EA] [a] Panamax [SW] [a] Paralgin [FM]

▪ PARACETAMOL + CODEINE

paracetamol 500 mg + codeine phosphate 15 mg tablet, 20

4170L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	13.30	6.20	Prodeinextra [SW]

paracetamol 500 mg + codeine phosphate 8 mg tablet, 40

4275B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	14.13	6.20	Panamax Co. 40 [SW]

paracetamol 500 mg + codeine phosphate 8 mg tablet, 50

4171M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	16.02	6.20	Codalgin [FM]

paracetamol 500 mg + codeine phosphate hemihydrate 15 mg tablet, 20

10186D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	13.30	6.20	Pharmacy Action Paracetamol Plus Codeine [GQ]

Other analgesics and antipyretics

▪ GABAPENTIN

Authority required

Refractory neuropathic pain

Clinical criteria:

The condition must be unable to be controlled by other drugs.

gabapentin 100 mg capsule, 100

4591P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	15.05	6.20	[a] APO-Gabapentin [TX] [a] Neurontin [PF]	[a] Gabapentin Aspen 100 [RW] [a] Nupentin 100 [AF]

gabapentin 300 mg capsule, 100

4592Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	25.89	6.20	[a] Gabapentin 300 [CR] [a] Gabapentin GH [GQ] [a] GenRx Gabapentin [GX] [a] Nupentin 300 [AF]	[a] Gabapentin Aspen 300 [RW] [a] Gantin [EA] [a] Neurontin [PF]

gabapentin 400 mg capsule, 100

4593R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	31.52	6.20	[a] Gabapentin 400 [CR] [a] Gabapentin GH [GQ] [a] GenRx Gabapentin [GX] [a] Nupentin 400 [AF]	[a] Gabapentin Aspen 400 [RW] [a] Gantin [EA] [a] Neurontin [PF]

gabapentin 600 mg tablet, 100

4594T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	43.91	6.20	[a] Gabapentin AN [EA] [a] GenRx Gabapentin [GX] [a] Nupentin Tabs [AF]	[a] Gabapentin Aspen 600 [RW] [a] Neurontin [PF]

gabapentin 800 mg tablet, 100

4595W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	55.07	6.20	[a] Gabapentin AN [EA] [a] Gantin [ED] [a] Neurontin [PF]	[a] Gabapentin Aspen 800 [RW] [a] GenRx Gabapentin [GX] [a] Nupentin Tabs [AF]

▪ PSYCHOLEPTICS

ANXIOLYTICS

Benzodiazepine derivatives

▪ BROMAZEPAM

Note This drug should not be used as the first line of treatment.

Note Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate.

Note Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

Authority required

Terminal disease

Clinical criteria:

The treatment must be for the short-term, AND

Patient must be receiving palliative care.

Authority required

Refractory phobic or anxiety states

Clinical criteria:

The treatment must be for the short-term.

bromazepam 3 mg tablet, 30

4150K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*30.49	6.20	Lexotan [RO]

bromazepam 6 mg tablet, 30

4151L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*36.23	6.20	Lexotan [RO]

Azaspirodecanedione derivatives

▪ BUSPIRONE

Authority required

Anxiety

Clinical criteria:

The treatment must be for the short-term.

buspirone hydrochloride 10 mg tablet, 50

4145E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	54.34	6.20	Buspar [QA]

buspirone hydrochloride 5 mg tablet, 50

4144D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	37.87	6.20	Buspar [QA]

HYPNOTICS AND SEDATIVES

Benzodiazepine derivatives

▪ FLUNITRAZEPAM

Note This drug should not be used as the first line of treatment.

Note Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate.

Note Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

Authority required

Terminal disease

Clinical criteria:

The treatment must be for the short-term, AND

Patient must be receiving palliative care.

Authority required

Refractory phobic or anxiety states

Clinical criteria:

The treatment must be for the short-term.

flunitrazepam 1 mg tablet, 30

4216X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	18.33	6.20	Hypnodorm [AF]

Benzodiazepine related drugs

▪ ZOPICLONE

Restricted benefit

Insomnia

Clinical criteria:

The treatment must be for the short-term.

zopiclone 7.5 mg tablet, 30

4522B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	23.76	6.20	[a] APO-Zopiclone [TX] [a] Imrest [AF]	[a] Chem mart Zopiclone [CH] [a] Terry White Chemists Zopiclone [TW]
			..	26.50	6.20	[a] Imovane [SW]	

▪ OTHER NERVOUS SYSTEM DRUGS

DRUGS USED IN ADDICTIVE DISORDERS

Drugs used in nicotine dependence

▪ NICOTINE

Note Studies have shown that successful therapy with this drug is enhanced by patient participation in a support and counselling program.

Authority required

Patients who have indicated that they are ready to cease smoking and who have entered a support and counselling program

nicotine 10 mg/16 hours patch, 7

4577X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*54.29	6.20	Nicorette Patch [JT]

nicotine 14 mg/24 hours patch, 7

4572P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*54.07	6.20	QuitX [AF]
			..	*67.09	6.20	Nicabate CQ 14 [GC]

nicotine 15 mg/16 hours patch, 7

4578Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	2	..	*59.11	6.20	Nicorette Patch [JT]

nicotine 21 mg/24 hours patch, 7

4573Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	2	..	*57.03	6.20	QuitX [AF]
			..	*67.09	6.20	Nicabate CQ 21 [GC]

nicotine 5 mg/16 hours patch, 7

4576W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*50.31	6.20	Nicorette Patch [JT]

nicotine 7 mg/24 hours patch, 7

4571N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*50.91	6.20	QuitX [AF]

ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS

ANTHELMINTICS

ANTINEMATODAL AGENTS

Benzimidazole derivatives

- **MEBENDAZOLE**

mebendazole 100 mg tablet, 6

4325P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	17.81	6.20	Vermox [IA]

RESPIRATORY SYSTEM

NASAL PREPARATIONS

DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE

Sympathomimetics, plain

- **OXYMETAZOLINE**

oxymetazoline hydrochloride 0.05% nasal spray, 15 mL

4378K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	19.75	6.20	Drixine [BN]

oxymetazoline hydrochloride 0.05% nasal spray, 18 mL

4379L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	19.41	6.20	Logicin Rapid Relief [QA]

Antiallergic agents, excl. corticosteroids

- **CROMOGLYCATE**

cromoglycate sodium 2% nasal spray, 26 mL

4468E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	5	..	24.76	6.20	Rynacrom [SW]

- **LEVOCABASTINE**

levocabastine 0.05% nasal spray, 100 actuations

4311X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	20.70	6.20	Livostin [JT]

Corticosteroids

- **BUDESONIDE**

Restricted benefit
Severe intractable rhinitis

budesonide 64 microgram/actuation nasal spray, 120 actuations

4092J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	38.48	6.20	Budamax Aqueous [PM]

Other nasal preparations

- **IPRATROPIUM**

Restricted benefit

Severe intractable rhinorrhoea, associated with perennial rhinitis, unresponsive to insufflated nasal steroids

ipratropium bromide anhydrous 21 microgram/actuation nasal spray, 180 actuations

4089F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	5	..	25.35	6.20	Atrovent Nasal Aqueous [BY]

ipratropium bromide anhydrous 42 microgram/actuation nasal spray, 180 actuations

4090G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	5	..	31.33	6.20	Atrovent Nasal Forte [BY]

NASAL DECONGESTANTS FOR SYSTEMIC USE

Sympathomimetics

- **PSEUDOEPHEDRINE**

pseudoephedrine hydrochloride 60 mg tablet, 12

4029C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	13.77	6.20	[a] Pharmacy Action Sinus & Nasal Decongestant Relief [GQ]
			..	14.42	6.20	[a] Logicin Sinus [QA]

COUGH AND COLD PREPARATIONS

EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

Expectorants

- **AMMONIUM + SENEGA ROOT**

ammonium bicarbonate 25 mg/mL + senega root 25 mg/mL oral liquid, 200 mL

4074K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	4	..	12.82	6.20	Gold Cross [BI]

COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS

Opium alkaloids and derivatives

- **PHOLCODINE**

pholcodine 1 mg/mL oral liquid, 100 mL

4071G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	12.68	6.20	Gold Cross [BI]
			..	17.54	6.20	Duro-Tuss [IA]

ANTIHISTAMINES FOR SYSTEMIC USE

ANTIHISTAMINES FOR SYSTEMIC USE

Piperazine derivatives

- **CETIRIZINE**

cetirizine hydrochloride 10 mg tablet, 30

4175R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	27.39	6.20	[a] Pharmacy Action Cetrelief [GQ]
			..	30.62	6.20	[a] Alzene [AF]
			..	33.42	6.20	Zilarex [SZ]
			..	39.14	6.20	[a] Zyrtec [JT]

Other antihistamines for systemic use

▪ FEXOFENADINE

fexofenadine hydrochloride 120 mg tablet, 30

4238C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	30.42	6.20	[a] Xergic [AF]
			..	35.02	6.20	[a] Fexal [SZ]
			..	46.63	6.20	[a] Telfast 120 [SW]

fexofenadine hydrochloride 60 mg tablet, 20

4237B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	3	..	..	*54.48	6.20	Telfast [SW]

▪ LORATADINE

loratadine 10 mg tablet, 30

4313B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	29.82	6.20	[a] Pharmacy Action Lorastyne [GQ]
			..	33.52	6.20	[a] Allereze [AF]
			..	43.15	6.20	[a] Lorano [SZ]
			..	45.42	6.20	[a] Claratyne [BN]

▪ SENSORY ORGANS

▪ OPHTHALMOLOGICALS

DECONGESTANTS AND ANTIALLERGICS

Sympathomimetics used as decongestants

▪ NAPHAZOLINE

naphazoline hydrochloride 0.1% eye drops, 15 mL

4035J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	17.96	6.20	Albalon Liquifilm [AG]

▪ NAPHAZOLINE + ANTAZOLINE

naphazoline hydrochloride 0.05% + antazoline phosphate 0.5% eye drops, 15 mL

4032F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	17.71	6.20	Albalon-A [AG]

Other antiallergics

▪ LEVOCABASTINE

levocabastine 0.05% eye drops, 4 mL

4310W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	20.70	6.20	Livostin [JT]

▪ OTOLOGICALS

OTHER OTOLOGICALS

Indifferent preparations

▪ CARBAMIDE PEROXIDE

carbamide peroxide 6.5% ear drops, 12 mL

4176T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	19.90	6.20	Ear Clear for Ear Wax Removal [KY]

▪ DICHLOROBENZENE WITH CHLORBUTOL AND ARACHIS OIL

DICHLOROBENZENE with CHLORBUTOL and ARACHIS OIL Ear drops, ortho-dichlorobenzene 140 mg per mL, para-dichlorobenzene 20 mg per mL, chlorbutol 50 mg per mL, arachis oil 573 mg per mL, 10 mL, 1

4180B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	17.08	6.20	Cerumol [UN]

▪ DOCUSATE

docusate sodium 0.5% ear drops, 10 mL

4199B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	17.42	6.20	Waxsol [HM]

▪ VARIOUS

▪ ALL OTHER THERAPEUTIC PRODUCTS

ALL OTHER THERAPEUTIC PRODUCTS

Drugs for treatment of hyperkalemia and hyperphosphatemia

▪ POLYSTYRENE SULFONATE SODIUM

polystyrene sulfonate sodium 999.3 mg/g powder, 454 g

4470G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	69.24	6.20	Resonium-A [SW]

▪ ALL OTHER NON-THERAPEUTIC PRODUCTS

ALL OTHER NON-THERAPEUTIC PRODUCTS

▪ LUBRICATING AGENT

lubricating agent jelly, 100 g

4306P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	13.65	6.20	Lubri-Gel [PP]

Other non-therapeutic auxiliary products

▪ BANDAGE ABSORBENT WOOL

bandage absorbent wool 10 cm x 3 m bandage, 1

4653X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	22.51	6.20	Surepress 650948 [CC]

▪ BANDAGE CALICO

bandage calico large bandage: triangular, 1

4717G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	16.43	6.20	Handy 36361414 [BV]

▪ BANDAGE COMPRESSION

Note Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

BANDAGE-COMPRESSION Bandage, short stretch, 8 cm x 2.6 m, 1

4654Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	5	..	..	*76.23	6.20	Comprilan 01027-00 [BV]

bandage compression 10 cm x 3 m bandage: high stretch, 1

4748X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	5	..	..	*70.88	6.20	Surepress 650947 [CC]
			..	*149.18	6.20	Tensopress 71723-00 [BV]

▪ BANDAGE COMPRESSION

Note Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

bandage compression bandage: four layer, 1

4598B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	5	..	..	*155.83	6.20	Profore Lite 66050415 [SN]

bandage compression bandage: four layer, 1

4658E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	5	..	..	*230.58	6.20	Profore 66050016 [SN]

▪ BANDAGE COMPRESSION

Note Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

Note Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

bandage compression 10 cm x 3.5 m bandage: high stretch, 1

4657D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5	..	..	*76.03	6.20	Setopress 3505 [MH]

▪ BANDAGE COMPRESSION

Note Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

Note Bandage can be left in situ for up to 7 days as per manufacturer's instructions.

Restricted benefit

Venous ulcer

Treatment Phase: Initial treatment

Restricted benefit

Venous ulcer

Treatment Phase: Continuing treatment

bandage compression bandage: two layer, 1

4050E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	42.18	6.20	Coban 2 [MM]

▪ BANDAGE RETENTION COHESIVE HEAVY

bandage retention cohesive heavy 10 cm x 1.3 m bandage, 1

4813H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*23.17	6.20	Peg 7423 [MM]

bandage retention cohesive heavy 10 cm x 2 m bandage, 1

4660G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*21.69	6.20	Coban 1584 [MM]

bandage retention cohesive heavy 15 cm x 1.3 m bandage, 1

4814J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*29.35	6.20	Peg 7425 [MM]

bandage retention cohesive heavy 5 cm x 1.3 m bandage, 1

4811F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*17.03	6.20	Peg 7420 [MM]

bandage retention cohesive heavy 7.5 cm x 1.3 m bandage, 1

4812G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*19.89	6.20	Peg 7422 [MM]

▪ BANDAGE RETENTION COHESIVE LIGHT

bandage retention cohesive light 10 cm x 2 m bandage, 1

4662J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*32.81	6.20	Handygauze Cohesive 8635 [BV]

bandage retention cohesive light 2.5 cm x 2 m bandage, 2

4718H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	16.56	6.20	Handygauze Cohesive 8631 [BV]

bandage retention cohesive light 6 cm x 2 m bandage, 1

4719J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*18.95	6.20	Handygauze Cohesive 8633 [BV]

▪ BANDAGE RETENTION COTTON CREPE

bandage retention cotton crepe 10 cm x 2.3 m bandage, 1

4729X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*26.91	6.20	Telfa 8254F [KE]
			..	*32.35	6.20	Tensocrepe 36301001 [BV]

bandage retention cotton crepe 5 cm x 2.3 m bandage, 1

4727T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*19.99	6.20	Telfa 8252F [KE]
			..	*22.65	6.20	Tensocrepe 36300501 [BV]

bandage retention cotton crepe 7.5 cm x 2.3 m bandage, 1

4728W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*24.17	6.20	Telfa 8253F [KE]
			..	*27.21	6.20	Tensocrepe 36307501 [BV]

▪ BANDAGE TUBULAR

bandage tubular size C (15 cm to 25 cm) bandage: straight, 1

4663K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	18.22	6.20	Elastoplast 2225 [BE]

bandage tubular size D (25 cm to 43 cm) bandage: straight, 1

4664L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	18.22	6.20	Elastoplast 2226 [BE]

bandage tubular size E (35 cm to 45 cm) bandage: straight, 1

4665M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	18.22	6.20	Elastoplast 2227 [BE]

▪ BANDAGE TUBULAR

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bandage tubular 10 cm x 1 m bandage, 1

4859R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	17.86	6.20	Tubigrip F 1548 [MH]

bandage tubular 6.25 cm x 1 m bandage, 1

4855M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	17.86	6.20	Tubigrip B 1520 [MH]

bandage tubular 6.75 cm x 1 m bandage, 1

4856N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	17.86	6.20	Tubigrip C 1545 [MH]

bandage tubular 7.5 cm x 1 m bandage, 1

4857P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	17.86	6.20	Tubigrip D 1546 [MH]

bandage tubular 8.75 cm x 1 m bandage, 1

4858Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	17.86	6.20	Tubigrip E 1547 [MH]

▪ BANDAGE TUBULAR FINGER

BANDAGE-TUBULAR (FINGER) Complete pack including applicator, 1

4798M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	20.29	6.20	Tubegauz 0501633 [SS]

▪ BANDAGE TUBULAR LIGHT WEIGHT

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(IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

bandage tubular light weight 10 m bandage: large limb size, 1

4673Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	29.30	6.20	Tubifast 2438 [MH]

bandage tubular light weight 10 m bandage: medium limb size, 1

4672X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	28.07	6.20	Tubifast 2436 [MH]

bandage tubular light weight 10 m bandage: small limb size, 1

4671W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	24.63	6.20	Tubifast 2434 [MH]

▪ BANDAGE TUBULAR LONG STOCKING

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bandage tubular long stocking bandage: XX/large size, 1

4675C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*37.15	6.20	Tubigrip 1486 [MH]

bandage tubular long stocking bandage: large size, 1

4799N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*37.13	6.20	Tubigrip 1484 [MH]

bandage tubular long stocking bandage: medium size, 1

4797L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*37.13	6.20	Tubigrip 1483 [MH]

bandage tubular long stocking bandage: small size, 1

4674B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*37.13	6.20	Tubigrip 1482 [MH]

▪ BANDAGE TUBULAR SHORT STOCKING

Note Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

bandage tubular short stocking bandage: large D/E size, 1

4816L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*26.91	6.20	Tubigrip 1481 [MH]

bandage tubular short stocking bandage: medium C/D size, 1

4815K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*26.91	6.20	Tubigrip 1480 [MH]

bandage tubular short stocking bandage: small B/C size, 1

4661H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*26.91	6.20	Tubigrip 1479 [MH]

▪ BANDAGE ZINC PASTE

Note Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

bandage zinc paste 10 cm x 9.1 m bandage, 1

4670T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	3	..	*29.87	6.20	Flexidress 650941 [CC]

▪ BANDAGE ZINC PASTE

Note Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

Note Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions

(IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

bandage zinc paste 7.5 cm x 6 m bandage, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4669R	2	3	..	*30.63	6.20	Steripaste 3610 [MH]

▪ BANDAGE ZINC PASTE

Note Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

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bandage zinc paste 7.5 cm x 6 m bandage, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4750B	2	3	..	*79.43	6.20	Viscopaste 4948 [SN]

bandage zinc paste 80 cm (stockings) bandage, 4

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4760M	‡1	3	..	91.02	6.20	ZipZoc 66000747 [SN]

▪ BETAINE + POLYAMINOPROPYL BIGUANIDE

betaine 0.1% + polyaminopropyl biguanide 0.1% solution, 6 x 40 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2525X	1	..	..	28.03	6.20	Prontosan Wound Irrigation Solution [BR]

▪ CADEXOMER-IODINE

Note Suitable for yellow sloughy infected and malodorous wounds.

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DRESSING with CADEXOMER IODINE Sheets 17 g (10 cm x 8 cm), 2, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4937W	‡1	..	..	159.57	6.20	Iodosorb 66051360 [SN]

DRESSING with CADEXOMER IODINE Sheets 5 g (6 cm x 4 cm), 5, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4935R	‡1	2	..	106.11	6.20	Iodosorb 66051330 [SN]

cadexomer-iodine 3 g powder: dusting sterile, 7 sachets

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4931M	‡1	2	..	71.05	6.20	Iodosorb Powder 66051070 [SN]

cadexomer-iodine 50% ointment, 2 x 20 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4933P	‡1	2	..	111.03	6.20	Iodosorb Ointment 66051230 [SN]

cadexomer-iodine 50% ointment, 4 x 10 g

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4932N	‡1	2	..	112.04	6.20	Iodosorb Ointment 66051240 [SN]

cadexomer-iodine 8 cm x 6 cm dressing, 3 x 10 g sheet

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4936T	‡1	2	..	151.62	6.20	Iodosorb 66051340 [SN]

▪ DRESSING ACTIVATED CHARCOAL MALODOROUS WOUND

dressing activated charcoal malodorous wound 10 cm x 10 cm dressing, 10

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
4742N	‡1	..	..	76.38	6.20	CarboFLEX 403202 [CC]

dressing activated charcoal malodorous wound 10.5 cm x 10.5 cm dressing, 1

4681J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	10	..	..	*96.33	6.20	Actisorb Plus MAP105 [KI]

dressing activated charcoal malodorous wound 15 cm x 20 cm dressing, 5

4743P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	86.28	6.20	CarboFLEX 403204 [CC]

▪ DRESSING ALGINATE CAVITY WOUND

Note This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 1

4832H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	10	..	..	*103.83	6.20	Sorbsan 1411 [UM]

DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 5

1905G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*109.37	6.20	Kaltostat 168117 [CC]

▪ DRESSING ALGINATE CAVITY WOUND

Note This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

Note Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

dressing alginate cavity wound 2 g (40 cm) rope, 6 x 2 g

4682K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*129.79	6.20	Comfeel SeaSorb Filler 3740 [CT]

▪ DRESSING ALGINATE SUPERFICIAL WOUND

Note This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

dressing alginate superficial wound 7.5 cm x 12 cm dressing, 10

4683L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	87.38	6.20	Kaltostat 168212 [CC]

▪ DRESSING ALGINATE SUPERFICIAL WOUND

Note This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

dressing alginate superficial wound 10 cm x 10 cm dressing, 10

4700J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	104.59	6.20	Algisite M 66000520 [SN]

dressing alginate superficial wound 15 cm x 20 cm dressing, 10

4691X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	250.74	6.20	Algisite M 66000521 [SN]

dressing alginate superficial wound 5 cm x 5 cm dressing, 10

4699H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	48.90	6.20	Kaltostat 168210 [CC]
			..	55.86	6.20	Algisite M 66000519 [SN]

▪ DRESSING ALGINATE SUPERFICIAL WOUND

Note This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

Note Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky

on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

dressing alginate superficial wound 10 cm x 10 cm dressing, 1

4831G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	10	1	..	*81.33	6.20	Sorbsan 1410 [UM]
			..	*86.53	6.20	Comfeel SeaSorb Dressing 3710 [CT]

dressing alginate superficial wound 5 cm x 5 cm dressing, 1

4684M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	10	1	..	*46.43	6.20	Comfeel SeaSorb Dressing 3705 [CT]

▪ DRESSING FILM

dressing film 10 cm x 12 cm dressing, 4

4687Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	21.92	6.20	Nexcare Tegaderm Transparent H1626 [MM]

dressing film 15 cm x 20 cm dressing, 1

4688R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	6	..	..	*31.47	6.20	Tegaderm Transparent 1628 [MM]

dressing film 6 cm x 7 cm dressing, 8

4686P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	18.44	6.20	Nexcare Tegaderm Transparent H1624 [MM]

▪ DRESSING FILM

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dressing film 10 cm x 12 cm dressing, 10

4893M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	35.22	6.20	Op-Site Flexigrid 4629 [SN]

▪ DRESSING FILM ISLAND

dressing film island 5 cm x 7 cm dressing, 1

4689T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	10	..	..	*18.93	6.20	Tegaderm Transparent Island 3582 [MM]

dressing film island 9 cm x 10 cm dressing, 1

4690W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	10	..	..	*28.93	6.20	Tegaderm Transparent Island 3586 [MM]

▪ DRESSING FILM ISLAND

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dressing film island 5 cm x 7.2 cm dressing, 5

4898T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*30.91	6.20	Cutifilm Plus 36361370 [SN]

dressing film island 8 cm x 10 cm dressing, 5

4899W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*46.63	6.20	Cutifilm Plus 36361371 [SN]

▪ DRESSING FOAM HEAVY EXUDATE

Note This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

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dressing foam heavy exudate 10 cm x 10 cm dressing, 10

4795J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	130.04	6.20	Allevyn 66007637 [SN]

▪ DRESSING FOAM MODERATE EXUDATE

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dressing foam moderate exudate cavity conforming foam, 20 g sachet

4694C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	1	..	94.67	6.20	Cavicare 4563 [SN]

▪ DRESSING FOAM MODERATE EXUDATE

Note This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

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dressing foam moderate exudate 12.5 cm x 12.5 cm dressing, 10

4590N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	129.97	6.20	Allevyn Adhesive 66000044 [SN]

▪ DRESSING FOAM WITH SILICONE

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dressing foam with silicone 10.3 cm x 10.3 cm dressing, 10

10017F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	55.83	6.20	Allevyn Life 66801067 [SN]

dressing foam with silicone 12.9 cm x 12.9 cm dressing, 10

10029W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	78.54	6.20	Allevyn Life 66801068 [SN]

dressing foam with silicone 15.4 cm x 15.4 cm dressing, 10

10023M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	107.51	6.20	Allevyn Life 66801069 [SN]

dressing foam with silicone 21 cm x 21 cm dressing, 10

10021K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	212.77	6.20	Allevyn Life 66801070 [SN]

▪ DRESSING FOAM WITH SILICONE AND SILVER

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Authority required

Wounds

Clinical criteria:

Patient must have a wound where there is evidence of critical colonisation; OR

Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

dressing foam with silicone and silver 10 cm x 10 cm dressing, 5

2439J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	103.95	6.20	Mepilex Ag [MH]

dressing foam with silicone and silver 10 cm x 10 cm dressing, 5

2470B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	111.00	6.20	Mepilex Border Ag [MH]

▪ DRESSING FOAM WITH SILICONE HEAVY EXUDATE

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dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 10

4196W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	74.07	6.20	Allevyn Gentle 66800248 [SN]

dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 10

4230P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	74.07	6.20	Allevyn Gentle Border 66800270 [SN]

dressing foam with silicone heavy exudate 7.5 cm x 7.5 cm dressing, 10

4207K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	52.86	6.20	Allevyn Gentle Border 66800269 [SN]

▪ DRESSING FOAM WITH SILICONE HEAVY EXUDATE

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dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 5

4643J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	42.18	6.20	Mepilex Border 295300 [MH]

dressing foam with silicone heavy exudate 7.5 cm x 7.5 cm dressing, 5

4642H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	31.59	6.20	Mepilex Border 295200 [MH]

▪ DRESSING FOAM WITH SILICONE LIGHT EXUDATE

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dressing foam with silicone light exudate 10 cm x 10 cm dressing, 5

4645L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	38.06	6.20	Mepilex Lite 284100 [MH]

dressing foam with silicone light exudate 6 cm x 8.5 cm dressing, 5

4644K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	29.24	6.20	Mepilex Lite 284000 [MH]

▪ DRESSING FOAM WITH SILICONE MODERATE EXUDATE

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dressing foam with silicone moderate exudate 10 cm x 10 cm dressing, 5

4626L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	42.18	6.20	Mepilex 294100 [MH]

▪ DRESSING FOAM WITH SILVER

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Authority required

Wounds

Clinical criteria:

Patient must have a wound where there is evidence of critical colonisation; OR

Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

dressing foam with silver 10 cm x 10 cm dressing, 10

4255Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	196.81	6.20	Allevyn Ag Adhesive 66800075 [SN]

dressing foam with silver 10 cm x 10 cm dressing, 10

4259E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	200.63	6.20	Allevyn Ag Non-Adhesive 66800086 [SN]

dressing foam with silver 10 cm x 10 cm dressing, 10

4266M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	196.81	6.20	Allevyn Ag Gentle Border 66800461 [SN]

dressing foam with silver 12.5 cm x 12.5 cm dressing, 10

4258D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	244.97	6.20	Allevyn Ag Adhesive 66800078 [SN]

dressing foam with silver 12.5 cm x 12.5 cm dressing, 10

4270R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	244.97	6.20	Allevyn Ag Gentle Border 66800462 [SN]

dressing foam with silver 7.5 cm x 7.5 cm dressing, 10

4252T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	133.61	6.20	Allevyn Ag Adhesive 66800073 [SN]

dressing foam with silver 7.5 cm x 7.5 cm dressing, 10

4263J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	133.61	6.20	Allevyn Ag Gentle Border 66800460 [SN]

▪ DRESSING GAUZE ABSORBENT

dressing gauze absorbent 10 cm x 10 cm pad, 100

4708T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	31.75	6.20	Handy 71117-06 [BV]

dressing gauze absorbent 5 cm x 5 cm pad, 100

4707R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	18.02	6.20	Handy 71117-05 [BV]

▪ DRESSING GAUZE EYE

dressing gauze eye pad, 12 pads

4768Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	15.99	6.20	Curity 4112 [KE]

▪ DRESSING GAUZE PARAFFIN

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

dressing gauze paraffin 10 cm x 10 cm dressing, 10

4759L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	23.64	6.20	Jelonet 7404 [SN]

▪ DRESSING GAUZE PARAFFIN WITH CHLORHEXIDINE ACETATE

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

dressing gauze paraffin with chlorhexidine acetate 10 cm x 10 cm dressing, 10

4845B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	30.02	6.20	Bactigras 7457 [SN]

▪ DRESSING HYDROACTIVE DEBRIDEMENT

Note Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 4 cm, 10, 1

4949L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	81.75	6.20	TenderWet 24 Active 609210 [HR]

DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 5.5 cm, 10, 1

4948K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	83.61	6.20	TenderWet Active Cavity 609272 [HR]

DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 7.5 cm x 7.5 cm, 10, 1

4950M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	109.35	6.20	TenderWet 24 Active 609213 [HR]

▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM

dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 10 cm x 10 cm (foam alternative) dressing, 10

4692Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	54.40	6.20	CombiDERM 651031 [CC]

dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 11 cm x 11 cm dressing: island, 10 dressings

4695D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	105.71	6.20	Tielle MTL101E [KI]

dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 18 cm (foam alternative) dressing, 5

4693B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	69.78	6.20	CombiDERM 651027 [CC]

dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm dressing: island, 5 dressings

4696E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	128.07	6.20	Tielle MTL103 [KI]

▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM

Note Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 10 cm x 10 cm pad: waterproof, 10

4927H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	84.52	6.20	Biatain Non-adhesive 3410 [CT]

dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 12 cm x 12 cm pad: waterproof, 10

4929K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	92.72	6.20	Biatain Adhesive 3420 [CT]

dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 15 cm pad: waterproof, 5

4928J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	83.17	6.20	Biatain Non-adhesive 3413 [CT]

dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm pad: waterproof, 5

4930L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	2	..	89.87	6.20	Biatain Adhesive 3423 [CT]

▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND LIGHT EXUDATE

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

dressing hydroactive superficial wound light exudate 10 cm x 10 cm dressing, 5

4906F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	1	..	*111.83	6.20	Allevyn Thin 66047578 [SN]

dressing hydroactive superficial wound light exudate 5 cm x 6 cm dressing, 10

4905E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	62.91	6.20	Allevyn Thin 66047576 [SN]

▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND MODERATE EXUDATE

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dressing hydroactive superficial wound moderate exudate 10 cm x 10 cm dressing, 5

4886E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	1	..	*85.15	6.20	Cutinova Hydro 66047443 [SN]

dressing hydroactive superficial wound moderate exudate 5 cm x 6 cm dressing, 10

4885D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	52.04	6.20	Cutinova Hydro 66047441 [SN]

▪ DRESSING HYDROCOLLOID CAVITY WOUND

Note This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

dressing hydrocolloid cavity wound paste, 30 g

4896Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	10	..	..	*136.53	6.20	DuoDERM Paste H7930 [CC]

▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE

Note This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

dressing hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10

4907G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	69.78	6.20	DuoDERM Extra Thin H7955 [CC]

▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE

Note This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

Note Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

dressing hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10

4924E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	68.02	6.20	Comfeel Plus Transparent 3533 [CT]

dressing hydrocolloid superficial wound light exudate 5 cm x 7 cm dressing, 10

4888G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	41.22	6.20	Comfeel Plus Transparent 3530 [CT]

dressing hydrocolloid superficial wound light exudate 9 cm x 14 cm dressing, 10

4889H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	81.42	6.20	Comfeel Plus Transparent 3536 [CT]

▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND LIGHT EXUDATE

Note This dressing should be applied to a thickness of 3 mm to 5 mm. It should be covered with a hydrocolloid dressing and may be left in place for up to 7 days.

Note Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

dressing hydrocolloid superficial wound light exudate 10 cm x 10 cm dressing, 10

4947J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	47.65	6.20	Hydrocoll Thin 900758 [HR]

▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

Note This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 5

4897R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	1	..	*78.59	6.20	DuoDERM CGF H7660 [CC]

dressing hydrocolloid superficial wound moderate exudate 20 cm x 20 cm dressing, 5

4920Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	1	..	*208.95	6.20	DuoDERM CGF H7662 [CC]

▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

Note This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

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dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 10

4921B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	86.04	6.20	Replicare Ultra 66000434 [SN]

▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

Note This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

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dressing hydrocolloid superficial wound moderate exudate 10 cm x 10 cm dressing, 10

4945G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	47.65	6.20	Hydrocoll 900744 [HR]

dressing hydrocolloid superficial wound moderate exudate 15 cm x 15 cm dressing, 10

4946H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	86.32	6.20	Hydrocoll 900936 [HR]

▪ DRESSING HYDROCOLLOID SUPERFICIAL WOUND MODERATE EXUDATE

Note This dressing should remain in place until saturated or strike through occurs for a maximum of 7 days.

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DRESSING-HYDROCOLLOID (SUPERFICIAL WOUND-MODERATE EXUDATE) Dressings with alginate 10 cm x 10 cm, 10, 1

4923D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	79.13	6.20	Comfeel Plus Ulcer Dressing 3110 [CT]

dressing hydrocolloid superficial wound moderate exudate 10cm (round) dressing, 1

4679G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	5	..	..	*58.78	6.20	Comfeel Plus Pressure Relieving 3353 [CT]

dressing hydrocolloid superficial wound moderate exudate 7cm (butterfly shape) dressing, 1

4678F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	5	..	..	*54.68	6.20	Comfeel Plus Pressure Relieving 3350 [CT]

▪ DRESSING HYDROFIBRE ALTERNATE TO ALGINATES

dressing hydrofibre alternate to alginates 10 cm x 10 cm dressing, 10

2797F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	96.38	6.20	Aquacel Extra 420672 [CC]

dressing hydrofibre alternate to alginates 15 cm x 15 cm dressing, 5

2803M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	1	..	*194.85	6.20	Aquacel Extra 420673 [CC]

dressing hydrofibre alternate to alginates 2 g (30 cm) rope, 5 x 2 g

4698G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	80.68	6.20	Aquacel 403770 [CC]

▪ DRESSING HYDROFIBRE GELLING FIBRE

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dressing hydrofibre gelling fibre 10 cm x 10 cm dressing, 10

2486W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	95.36	6.20	Durafiber 66800560 [SN]

dressing hydrofibre gelling fibre 15 cm x 15 cm dressing, 5

2445Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡2	1	..	*193.91	6.20	Durafiber 66800561 [SN]

dressing hydrofibre gelling fibre 2 cm x 45 cm rope, 5

2462N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	80.32	6.20	Durafiber 66800563 [SN]

▪ DRESSING HYDROFIBRE WITH SILVER

Authority required

Wounds

Clinical criteria:

Patient must have a wound where there is evidence of critical colonisation; OR

Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

dressing hydrofibre with silver 10 cm x 10 cm dressing, 10

10097K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	250.08	6.20	Aquacel Ag 403708 [CC]

dressing hydrofibre with silver 15 cm x 15 cm dressing, 5

10098L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	267.72	6.20	Aquacel Ag 403710 [CC]

dressing hydrofibre with silver 2 cm x 45 cm rope, 5

10105W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	211.14	6.20	Aquacel Ag 403771 [CC]

▪ DRESSING HYDROGEL

dressing hydrogel 10 cm x 10 cm dressing, 20

2471C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	..	..	108.26	6.20	Sorbact Absorption Dressing S98222 [QL]

▪ DRESSING HYDROGEL AMORPHOUS

Note This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

dressing hydrogel amorphous gel, 3 x 30 g

4913N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	3	1	..	*92.85	6.20	DuoDERM Gel H7987 [CC]

dressing hydrogel amorphous gel, 50 g

4914P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	3	3	..	*33.63	6.20	Solugel 10336 [JJ]

▪ DRESSING HYDROGEL AMORPHOUS

Note This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

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dressing hydrogel amorphous gel, 10 x 15 g

4912M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	1	..	63.20	6.20	DuoDERM Gel H7990 [CC]
			..	70.12	6.20	Comfeel Purilon Gel 3900 [CT]

▪ DRESSING HYDROGEL AMORPHOUS

Note This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

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dressing hydrogel amorphous gel, 25 g

4894N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	4	3	..	*67.45	6.20	Intrasite Gel 7313 [SN]

dressing hydrogel amorphous gel, 50 g

4599C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	3	3	..	*32.91	6.20	SoloSite Gel 36361338 [SN]

▪ DRESSING HYDROGEL FOAM

dressing hydrogel foam 10 cm x 10 cm dressing, 10

2533H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	76.81	6.20	Sorbact Foam Dressing S98310 [QL]

▪ DRESSING HYDROGEL RIBBON

dressing hydrogel ribbon 1 cm x 50 cm dressing, 20

2512F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	111.76	6.20	Sorbact Ribbon Gauze S98118 [QL]

dressing hydrogel ribbon 5 cm x 200 cm dressing, 10

2529D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	..	..	108.26	6.20	Sorbact Ribbon Gauze S98120 [QL]

▪ DRESSING HYDROGEL SHEET

Note This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

dressing hydrogel sheet 9.5 cm x 10.2 cm dressing, 5

4911L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*80.23	6.20	Nu-Gel 2497 [KI]

▪ DRESSING HYDROGEL SHEET

Note This dressing should be applied to a thickness of 3 mm to 5 mm and remain in situ in infected wounds for 24 hours and in clean wounds for up to 3 days. It should be covered with a secondary dressing such as foam or film. It should not be covered with gauze or combine.

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dressing hydrogel sheet 10 cm x 10 cm dressing, 5

4806Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	..	..	*52.79	6.20	Hydrosorb 900854 [HR]

▪ DRESSING NON ADHERENT

dressing non adherent 5 cm x 7.5 cm dressing, 10

4755G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	14.42	6.20	Telfa 1970C [KE]

dressing non adherent 7.5 cm x 10 cm dressing, 6

4758K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	14.60	6.20	Telfa 2140C [KE]

dressing non adherent 7.5 cm x 10 cm dressing, 6

4844Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	2	..	15.29	6.20	Telfa 7650C [KE]

▪ DRESSING NON ADHERENT

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DRESSING SELF ADHESIVE NON-ADHERENT DRY ABSORBENT Dressings, non-woven, with silicone 5 cm x 7.5 cm, 10, 1

4243H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	62.42	6.20	Mepitel 290510 [MH]

DRESSING SELF ADHESIVE NON-ADHERENT DRY ABSORBENT Dressings, non-woven, with silicone 7.5 cm x 10 cm, 10, 1

4244J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	102.42	6.20	Mepitel 290710 [MH]

▪ DRESSING NON ADHERENT

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dressing non adherent 7.5 cm x 10 cm dressing, 10

4944F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	18.09	6.20	Atrauman 499513 [HR]

▪ DRESSING NON ADHERENT

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dressing non adherent 10 cm x 10 cm dressing, 10

4861W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	37.12	6.20	Melolin 66974933 [SN]

dressing non adherent 10 cm x 10 cm dressing, 5

4862X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*27.37	6.20	Cutilin Non-Stick Wound Pad 36361375 [SN]

dressing non adherent 5 cm x 5 cm dressing, 5

4819P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*18.77	6.20	Cutilin Non-Stick Wound Pad 36361374 [SN]

dressing non adherent 5 cm x 5 cm dressing, 5

4860T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	2	..	..	*19.95	6.20	Melolin 36361357 [SN]

▪ DRESSING TULLE NON GAUZE PARAFFIN

dressing tulle non gauze paraffin 7.6 cm x 7.6 cm dressing, 1

4909J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	10	1	..	*18.53	6.20	Adaptic 2012 [KI]

▪ DRESSING WITH SILVER

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Authority required

Wounds

Clinical criteria:

Patient must have a wound where there is evidence of critical colonisation; OR

Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

dressing with silver 10 cm x 10 cm dressing: hydroactive, 5

4646M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	164.47	6.20	Biatain Ag 9622 [CT]

dressing with silver 12.5 cm x 12.5 cm dressing: hydroactive, 5

4647N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	178.48	6.20	Biatain Ag 9632 [CT]

▪ DRESSING WITH SILVER

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Authority required
Wounds
Clinical criteria:
Patient must have a wound where there is evidence of critical colonisation; OR
Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

dressing with silver 10 cm x 10 cm dressing: tulle, 3

4648P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	43.28	6.20	Atrauman Ag 499572 [HR]

▪ GAUZE AND COTTON TISSUE COMBINE ROLL

gauze and cotton tissue combine roll 10 cm x 10 m roll: wrapped pack, 1 pack

4761N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	19.80	6.20	JJ 12010 [JJ]

gauze and cotton tissue combine roll 9 cm x 10 m roll: wrapped pack, 1 pack

4767X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	15.11	6.20	BSN 2902165 [BV]

▪ TAPE NON WOVEN RETENTION POLYACRYLATE

tape non woven retention polyacrylate 2.5 cm x 9.1 m tape, 1 roll

4915Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	16.03	6.20	Medipore 2961 [MM]

▪ TAPE NON WOVEN RETENTION POLYACRYLATE

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tape non woven retention polyacrylate 2.5 cm x 10 m tape, 1 roll

4917T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	14.44	6.20	Mefix 310250 [MH]

▪ TAPE PLASTER ADHESIVE ELASTIC

tape plaster adhesive elastic 2.5 cm x 2.5 m tape, 1 roll

4780N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	16.95	6.20	Leukoplast 01071-00 [BV]

tape plaster adhesive elastic 5 cm x 2.5 m tape, 1 roll

4781P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	22.89	6.20	Leukoplast 01072-00 [BV]

tape plaster adhesive elastic 7.5 cm x 2.5 m tape, 1 roll

4782Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	26.57	6.20	Leukoplast 01073-00 [BV]

▪ TAPE PLASTER ADHESIVE HYPOALLERGENIC

tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll

4783R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	14.36	6.20	Leukopor 2471 [BV]

tape plaster adhesive hypoallergenic 1.25 cm x 5 m tape, 1 roll

4785W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	14.65	6.20	Leukosilk 1021 [BV]

tape plaster adhesive hypoallergenic 1.9 cm x 5.4 m dispenser tape, 1 roll

4848E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	14.45	6.20	Nexcare Durable Cloth First Aid Tape 799 [MM]

tape plaster adhesive hypoallergenic 1.9 cm x 7.3 m dispenser tape, 1 roll

4849F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	14.45	6.20	Nexcare Gentle Paper First Aid Tape 789 [MM]

tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll

4787Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	17.30	6.20	Leukosilk 1022 [BV]

tape plaster adhesive hypoallergenic 2.5 cm x 5 m tape, 1 roll

4794H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	16.77	6.20	Leukopor 2472 [BV]

tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll

4788B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	19.80	6.20	Leukoflex 1124 [BV]

tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll

4789C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	21.12	6.20	Leukosilk 1024 [BV]

tape plaster adhesive hypoallergenic 5 cm x 5 m stretch tape, 1 roll

4790D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	20.29	6.20	Leukopor 2474 [BV]

▪ TAPE PLASTER ADHESIVE WITH SILICONE

Note Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

tape plaster adhesive with silicone 2 cm x 3 m tape, 1 roll

4239D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	23.42	6.20	Mepitac 298300 [MH]

tape plaster adhesive with silicone 4 cm x 1.5 m tape, 1 roll

4240E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	‡1	..	..	23.42	6.20	Mepitac 298400 [MH]

Extemporaneous Prepared Benefits

Drugs Tariff

Drug	Standard	Recovery Prices			
		Drug	0.1 g/mL $	1 g/mL $	10 g/mL $
Acacia Mucilage (by weight)	APF 15	0.01	0.10	0.77	6.81
Acacia, powdered	BP	0.02	0.17	1.37	12.22
Acetic Acid (33 per cent)	BP	0.01	0.06	0.45	3.97
Acetic Acid (6 per cent)	BP	0.01	0.02	0.14	1.22
Acetic Acid Glacial BP	BP	0.02	0.14	1.08	9.60
Acetone (use as additive only)	BP	0.02	0.15	1.19	10.58
Alum	BP	0.01	0.07	0.58	5.16
Aluminium Acetate Solution	BP	0.02	0.17	1.35	12.04
Anise Oil BP	BP	0.18	1.41	11.29	100.39
Anise Water Concentrated 1 in 40	BP	0.01	0.07	0.56	4.96
Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.03	0.25	2.21
Ascorbic Acid (for use only as an ingredient of ferrous sulfate mixtures)	BP	0.24	1.93	15.44	137.21
Aspirin	BP	0.07	0.58	4.67	41.49
Belladonna Tincture	BP	0.08	0.67	5.34	47.46
Benzocaine	BP	0.11	0.85	6.83	60.69
Benzoic Acid	BP	0.05	0.42	3.37	29.98
Benzoic Acid Compound Ointment	APF	0.02	0.15	1.23	10.94
Benzoic Acid Solution	BP	0.02	0.13	1.01	8.94
Benzoin Compound Tincture	BP	0.04	0.32	2.55	22.70
Boric Acid (use as additive only)	BP	0.02	0.14	1.14	10.10
Boric Acid, Olive Oil and Zinc Oxide Ointment	QHF	0.02	0.13	1.07	9.53
Calcium Hydroxide	BP	0.09	0.73	5.86	52.10
Calcium Hydroxide Solution	BP	0.01	0.02	0.15	1.34
Castor Oil (use as additive only)	BP	0.02	0.13	1.02	9.09
Cetomacrogol Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.04	0.32	2.84
Cetrimide Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.02	0.17	1.32	11.76
Chlorhexidine Acetate (use as additive only)	BP	0.62	4.97	39.76	353.42
Chlorhexidine Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.03	0.24	1.90	16.91
Chloroform (use as additive only)	BP	0.08	0.64	5.09	45.29
Chloroform Spirit	BP	0.01	0.08	0.62	5.54
Chloroform Water Concentrated 1 in 40	APF 15	0.01	0.10	0.76	6.77
Citric Acid Monohydrate	BP	0.03	0.25	1.99	17.73
Coal Tar	BP	0.22	1.73	13.85	123.09
Coal Tar Solution	BP	0.02	0.16	1.26	11.18
Cocaine Hydrochloride	BP	5.55	44.39	355.15	3156.88
Coconut Oil	BP	0.02	0.14	1.11	9.85
Codeine Linctus	APF	0.01	0.11	0.85	7.54
Codeine Phosphate (may only be prescribed in linctuses, mixtures or mixtures for children)	BP	1.95	15.63	125.00	1111.11
Collodion Flexible	BP	0.17	1.37	10.98	97.59
Dithranol	BP	4.47	35.73	285.80	2540.42
Emulsifying Ointment (for use only as a base combined with active ingredients)	BP	0.01	0.07	0.53	4.74
Ephedrine Hydrochloride (may only be prescribed in nasal instillations)	BP	1.68	13.45	107.56	956.05
Ethanol (90 per cent) (use as additive only)	BP	0.01	0.04	0.28	2.48

Drug	Standard	Recovery Prices			
Ethanol (96 per cent) (use as additive only)	BP	0.01	0.04	0.28	2.47
Ether Solvent (use as additive only)	BP	0.20	1.56	12.44	110.59
Eucalyptus Oil (use as additive only)	BP	0.02	0.18	1.41	12.50
Ferrous Sulfate	BP	0.16	1.29	10.29	91.49
Formaldehyde Solution	BP	0.06	0.48	3.81	33.88
Gentian Alkaline Mixture	APF	0.01	0.08	0.65	5.77
Glycerol	BP	0.01	0.11	0.86	7.69
Honey Purified (use as additive only)	BP 1993	0.01	0.03	0.25	2.24
Hydroxybenzoate Compound Solution	APF	0.08	0.65	5.17	45.95
Iodine	BP	0.33	2.64	21.10	187.53
Iodine Alcoholic Solution	BP	0.04	0.28	2.21	19.68
Iodine Aqueous Oral Solution	BP	0.04	0.33	2.62	23.28
Kaolin Mixture	BPC 1968	0.02	0.12	0.92	8.15
Kaolin and Opium Mixture	APF 14	0.01	0.10	0.79	7.04
Lactic Acid	BP	0.32	2.54	20.28	180.24
Lavender Spike Oil	BPC 1968	0.13	1.02	8.14	72.31
Liquorice Liquid Extract	BP	0.03	0.23	1.83	16.28
Magnesium Carbonate Light	BP	0.04	0.32	2.58	22.90
Magnesium Sulfate (may only be prescribed for other than oral use)	BP	0.01	0.03	0.21	1.87
Magnesium Trisilicate	BP	0.04	0.32	2.57	22.82
Menthol, Racemic or Levomenthol	BP	0.22	1.78	14.25	126.71
Methyl Hydroxybenzoate	BP	0.36	2.91	23.24	206.54
Methyl Hydroxybenzoate Solution	APF	0.04	0.32	2.52	22.42
Methylated Industrial Spirit (use as additive only)	BP	0.01	0.06	0.48	4.27
Olive Oil (use as additive only)	BP	0.02	0.13	1.07	9.48
Paraffin Hard	BP	0.04	0.29	2.32	20.59
Paraffin Light Liquid	BP	0.02	0.17	1.38	12.23
Paraffin Liquid (use as additive only)	BP	0.01	0.06	0.45	3.98
Paraffin Soft White	BP	0.01	0.05	0.41	3.66
Paraffin Soft Yellow	BP	0.01	0.05	0.41	3.66
Peppermint Oil (use as additive only)	BP	0.15	1.17	9.34	83.02
Peppermint Water Concentrated 1 in 40 (use as additive only)	APF 16	0.04	0.33	2.67	23.72
Phenobarbitone Sodium (may only be prescribed for the treatment of epilepsy)	BP	9.36	74.90	599.18	5326.01
Phenol Liquefied (not available for ear drops)	BP	0.11	0.91	7.24	64.40
Podophyllum Resin	BP	3.36	26.89	215.15	1912.41
Potassium Citrate	BP	0.02	0.17	1.35	12.00
Potassium Iodide	BP	0.10	0.82	6.58	58.49
Potassium Permanganate	BP	0.03	0.27	2.19	19.51
Propyl Hydroxybenzoate	BP	0.29	2.28	18.20	161.74
Propylene Glycol	BP	0.01	0.11	0.89	7.89
Red Syrup	APF 15	0.02	0.13	1.03	9.14
Resorcinol	BP	0.37	2.94	23.48	208.68
Salicylic Acid	BP	0.05	0.38	3.04	27.03
Salicylic Acid Ointment	APF	0.02	0.17	1.33	11.78
Salicylic Acid Ointment	BP	0.02	0.17	1.33	11.78
Simple Ointment (white) (for use only as a base combined with active ingredients)	BP	0.02	0.14	1.10	9.79
Simple Ointment (yellow) (for use only as a base combined with active ingredients)	BP	0.02	0.14	1.10	9.79
Sodium Bicarbonate	BP	0.01	0.11	0.86	7.64
Sodium Chloride	BP	0.02	0.15	1.18	10.46
Sodium Chloride Solution	BP	0.01	0.01	0.08	0.74
Sodium Citrate	BP	0.03	0.23	1.87	16.63
Sodium Thiosulfate (use as additive only)	BP	0.03	0.24	1.89	16.76
Starch	BP	0.02	0.15	1.23	10.90
Sulfur Ointment (for use only as a base combined with active ingredients)	BP 1980	0.02	0.15	1.19	10.60
Sulfur Precipitated	BP 1980	0.03	0.22	1.78	15.86
Syrup	BP	0.01	0.06	0.46	4.08
Talc Purified, sterilised	BP	0.03	0.26	2.08	18.52
Thymol	BP	0.26	2.06	16.48	146.45
Thymol Compound Mouth Wash	APF 15	0.02	0.13	1.03	9.16
Tragacanth Compound Powder	BP 1980	0.07	0.57	4.53	40.28
Tragacanth Mucilage	APF 13	0.01	0.06	0.44	3.89
Tragacanth Mucilage	BPC 1973	0.01	0.05	0.36	3.24
Tragacanth, powdered	BP	0.23	1.87	14.97	133.09

Drug	Standard	Recovery Prices			
Trichloroacetic Acid	BP 1980	0.36	2.86	22.87	203.31
Triethanolamine	BP	0.07	0.59	4.71	41.91
Water For Injections, sterilised (b) (extemporaneously prepared eye drops and eye lotions)	BP				
Water Purified	BP	0.01	0.01	0.07	0.61
Wool Alcohols Ointment (white) (for use only as a base combined with active ingredients)	BP	0.02	0.18	1.43	12.73
Wool Alcohols Ointment (yellow) (for use only as a base combined with active ingredients)	BP	0.02	0.18	1.43	12.73
Wool Fat	BP	0.02	0.19	1.50	13.33
Wool Fat Hydrous	BP	0.02	0.14	1.11	9.86
Zinc Compound Paste	BP	0.05	0.39	3.12	27.72
Zinc Cream (for use only as a base combined with active ingredients)	BP	0.01	0.08	0.60	5.33
Zinc Oxide	BP	0.02	0.15	1.18	10.50
Zinc Sulfate	BP	0.03	0.25	1.96	17.42
Zinc and Salicylic Acid Paste	BP	0.02	0.15	1.22	10.80

Container Prices

Type	Container	Price $
Dispensing Bottles	25mL	0.64
Dispensing Bottles	50mL	0.53
Dispensing Bottles	100mL	0.85
Dispensing Bottles	200mL	1.20
Dispensing Bottles	500mL	1.28
Poison Bottles	25mL	0.78
Poison Bottles	50mL	0.72
Poison Bottles	100mL	0.64
Poison Bottles	200mL	0.87
Poison Bottles	500mL	1.47
Dropper Containers (Glass)	15mL	1.12
Dropper Containers (Polythene)	15mL	0.98
Screw Cap Jars	25g	1.09
Screw Cap Jars	50g	1.18
Screw Cap Jars	100g	1.33
Screw Cap Jars	200g	0.85
Screw Cap Jars	500g	1.24

Standard Formula Preparations

Code	Item	Reference	Dispensed Price for Max Qty $	Maximum Recordable Value to Safety Net $
	Creams (Maximum Quantity 100 g and 1 Repeat)			
7502W	Salicylic Acid and Sulfur Aqueous	APF	13.55	15.08
	Dusting Powders (Maximum Quantity 100 g and 1 Repeat)			
7458M	Zinc, Starch and Talc	APF 15 & BPC 1973	26.30	27.83
	Ear Drops (Maximum Quantity 15 mL and 2 Repeats)			
7642F	Aluminium Acetate	APF	11.14	12.67
7643G	Aluminium Acetate	BP	11.89	13.42
7314Y	Sodium Bicarbonate	APF & BP	10.49	12.02
7313X	Spirit	APF	10.12	11.65
	Inhalations (Maximum Quantity 50 mL and 1 Repeat)			
7484X	Benzoin and Menthol	APF	24.26	25.79
7308P	Menthol	APF	12.89	14.42
7310R	Menthol and Eucalyptus	BP1980	13.81	15.34
	Linctuses containing Codeine Phosphate (Maximum Quantity 100 mL and 0 Repeat)			
7530H	Codeine	APF	17.27	18.80
	Lotions (Maximum Quantity 200 mL and 2 Repeats)			
7709R	Aluminium Acetate Aqueous	APF	12.61	14.14
	Mixtures, Other (Maximum Quantity 200 mL and 4 Repeats)			
7604F	Gentian Alkaline	APF	21.50	23.03
7348R	Kaolin	BPC 1968	26.26	27.79
7301G	Kaolin and Opium	APF 14	24.04	25.57
7342K	Magnesium Trisilicate	BPC 1968	18.82	20.35
7343L	Magnesium Trisilicate and Belladonna	BPC 1968	24.02	25.55
	Mouth Washes (Maximum Quantity 200 mL and 1 Repeat)			
7457L	Thymol Compound	APF 15	28.42	29.95
	Ointments, Waxes (Maximum Quantity 100 g and 1 Repeat)			
7914M	Benzoic Acid Compound	APF & BP	21.16	22.69
7902X	Boric Acid, Olive Oil and Zinc Oxide	QHF	19.75	21.28
7926E	Salicylic Acid	APF	22.00	23.53
7928G	Salicylic Acid (extemporaneous formula)	BP	22.00	23.53
	Paints (Maximum Quantity 25 mL and 1 Repeat)			
7567G	Podophyllin Compound	APF 16 & BP	116.87	38.30
7568H	Salicylic Acid	APF	38.03	38.30

Code	Item	Reference	Dispensed Price for Max Qty $	Maximum Recordable Value to Safety Net $
	Pastes, Other (Maximum Quantity 100 g and 1 Repeat)			
7558T	Zinc	APF & BP	37.94	38.30
	Powders for Internal Use (Maximum Quantity 100 g and 2 Repeats)			
7545D	Magnesium Trisilicate	BP	32.68	34.21

Table of Codes, Maximum Quantities, and Number of Repeats for Extemporaneously Prepared Benefits

Code	Preparation	Maximum Quantity	Number of Repeats
13Q	Creams	100 g	1
48M	Dusting Powders	100 g	1
15T	Ear Drops	15 mL	2
19B	Eye Drops containing Cocaine Hydrochloride	15 mL	..
22E	Eye Drops, Other	15 mL	5
23F	Eye Lotions	200 mL	2
29M	Inhalations	50 mL	1
64J	Linctuses containing Codeine Phosphate	100 mL	..
34T	Linctuses, Other	100 mL	2
39C	Lotions	200 mL	2
65K	Mixtures containing Codeine Phosphate	200 mL	..
66L	Mixtures for Children containing Codeine Phosphate	100 mL	..
41E	Mixtures for Children, Other	100 mL	4
40D	Mixtures, Other	200 mL	4
30N	Mouth Washes	200 mL	1
42F	Nasal Instillations	15 mL	2
43G	Ointments, Waxes	100 g	1
44H	Paints	25 mL	1
63H	Pastes containing Cocaine Hydrochloride	25 g	..
45J	Pastes, Other	100 g	1
49N	Powders for Internal Use	100 g	2
52R	Solutions	200 mL	2

Index of Manufacturers' Code

Code	Manufacturer
AB	Abbott Australasia Pty Ltd
AE	AFT Pharmaceuticals Pty Ltd
AF	Alphapharm Pty Ltd
AG	Allergan Australia Pty Limited
AL	Alphapharm Pty Ltd
AN	Amgen Australia Pty Limited
AP	AstraZeneca Pty Ltd
AQ	Alcon Laboratories (Australia) Pty Ltd
AS	Aspen Pharmacare Australia Pty Limited
AT	Actelion Pharmaceuticals Australia Pty Ltd
AV	sanofi-aventis Australia Pty Ltd
BB	Blackmores Limited
BD	Biogen Australia Pty Ltd
BE	Beiersdorf Australia Ltd
BG	Sandoz Pty Ltd
BI	Biotech Pharmaceuticals Pty Ltd
BN	Bayer Australia Ltd
BQ	Bristol-Myers Squibb Australia Pty Ltd
BR	B. Braun Australia Pty Ltd
BV	BSN medical (Aust.) Pty Ltd
BX	Baxter Healthcare Pty Limited
BY	Boehringer Ingelheim Pty Ltd
BZ	Boucher & Muir Pty Ltd
CC	ConvaTec A Division of Bristol-Myers Squibb Australia Pty Ltd
CF	CNS Pharma Pty Ltd
CH	Apotex Pty Ltd
CJ	Celgene Pty Limited
CR	Pharmacor Pty Limited
CS	Seqirus (Australia) Pty Ltd
CT	Coloplast Pty Ltd
CU	Care Pharmaceuticals Pty Limited
CX	Contact Lens Centre Australia Limited
DE	Stallergenes Australia Pty Ltd
DO	Aurobindo Pharma (Australia) Pty Limited
DQ	Church & Dwight (Australia) Pty Ltd
DV	Medical Developments International Limited
DZ	Medsurge Healthcare Pty Ltd
EA	Amneal Pharmaceuticals Pty Ltd
ED	Amneal Pharmaceuticals Pty Ltd
EF	Amneal Pharmaceuticals Pty Ltd
EH	Entra Health Systems Pty Ltd
EI	Eisai Australia Pty Ltd
EL	Eli Lilly Australia Pty Ltd
EO	Ego Pharmaceuticals Proprietary Limited
ER	Eris Pharmaceuticals (Australia) Pty Ltd
EU	Emerge Health Pty Ltd
EZ	Merz Australia Pty Ltd
FB	Pierre Fabre Medicament Australia Pty Ltd
FI	Boehringer Ingelheim Pty Ltd
FK	A. Menarini Australia Pty Limited
FM	Fawns and McAllan Proprietary Limited
FN	Fresenius Medical Care Australia Pty Ltd
FO	For Benefit Medicines Pty Ltd
FP	Ferring Pharmaceuticals Pty Limited
FR	Merck Sharp & Dohme (Australia) Pty Ltd
FZ	Pfizer Australia Pty Ltd
GA	Galderma Australia Pty Ltd
GC	GlaxoSmithKline Australia Pty Ltd
GH	Amdipharm Mercury (Australia) Pty Limited
GI	Gilead Sciences Pty Limited
GK	GlaxoSmithKline Australia Pty Ltd
GN	Actavis Pty Ltd
GO	BGP Products Pty Ltd
GQ	Generic Health Pty Ltd
GT	BGP Products Pty Ltd
GX	Apotex Pty Ltd
GZ	sanofi-aventis Australia Pty Ltd
HB	Besins Healthcare Australia Pty Ltd
HH	Hospira Pty Limited
HM	Meda Pharmaceuticals Pty Ltd
HR	Paul Hartmann Pty Ltd
HX	Sandoz Pty Ltd
IA	iNova Pharmaceuticals (Australia) Pty Limited
IB	Apotex Pty Ltd
IF	Infopia Australia Pty Ltd
IK	Medtronic Australasia Pty Ltd
IO	BioMarin Pharmaceutical Australia Pty Ltd
IQ	Alcon Laboratories (Australia) Pty Ltd
IR	Indivior Pty Ltd
IS	Ipsen Pty Ltd
IV	iNova Pharmaceuticals (Australia) Pty Limited
IX	Clinect Pty Ltd
IY	Clinect Pty Ltd
JC	Janssen-Cilag Pty Ltd
JJ	Johnson & Johnson Medical Pty Ltd
JO	Juno Pharmaceuticals Pty Ltd
JT	Johnson & Johnson Pacific Pty Limited
JU	Juno Pharmaceuticals Pty Ltd
KE	Kendall Australasia Pty Ltd
KI	KCI Medical Australia Pty Ltd
KP	Eli Lilly Australia Pty Ltd
KY	Key Pharmaceuticals Pty Ltd
LL	Astellas Pharma Australia Pty Ltd
LM	Link Medical Products Pty Ltd
LN	Aspen Pharmacare Australia Pty Limited
LO	Leo Pharma Pty Ltd
LS	Astellas Pharma Australia Pty Ltd
LU	Lundbeck Australia Pty Ltd
LX	Lawley Pharmaceuticals Pty Ltd
LY	Eli Lilly Australia Pty Ltd
MF	Mundipharma Pty Limited
MH	Molnlycke Health Care Pty Ltd
MK	Merck Sharp & Dohme (Australia) Pty Ltd
MM	3M Pharmaceuticals Australia Pty Ltd
MQ	Alphapharm Pty Ltd
MS	Abbott Australasia Pty Ltd
MT	Mentholatum Australasia Pty Ltd

Code	Manufacturer
MW	Biomed Aust Pty Limited
NA	National Diagnostic Products (Australia) Pty Limited
NC	Novartis Consumer Health Australasia Pty Ltd
NE	Norgine Pty Limited
NF	Novo Nordisk Pharmaceuticals Pty Limited
NI	Novo Nordisk Pharmaceuticals Pty Limited
NM	Novartis Pharmaceuticals Australia Pty Limited
NO	Novo Nordisk Pharmaceuticals Pty Limited
NQ	Takeda Pharmaceuticals Australia Pty Ltd
NT	Nestle Australia Ltd
NU	Nutricia Australia Pty Limited
NV	Novartis Pharmaceuticals Australia Pty Limited
NX	Nipro Australia Pty Ltd
OA	Orphan Australia Pty Ltd
OB	Oral B Laboratories Pty Ltd
OC	Accord Healthcare Pty Ltd
OE	Omegapharm Pty Ltd
OH	Orpharma Pty Ltd
OL	Owen Laboratories Division of Galderma Australia Pty Ltd
OM	Colgate Oral Care
ON	Orion Laboratories Pty Ltd
OS	Otsuka Australia Pharmaceutical Pty Ltd
OW	Arrow Pharma Pty Ltd
OZ	Medical Specialties Australia Unit Trust
PB	Pharmaco (Australia) Limited
PE	Allergan Australia Pty Limited
PF	Pfizer Australia Pty Ltd
PK	Fresenius Kabi Australia Pty Limited
PL	The Trustee for Virgo Unit Trust (trading as Phebra)
PM	Pharmaceutical Manufacturing Company Pty Limited
PP	Petrus Pharmaceuticals Pty Ltd
PQ	PMIP Pty Ltd
PX	Point of Care Diagnostics Australia Pty Ltd
PY	Procter & Gamble Pharmaceuticals Australia Pty Ltd
QA	Aspen Pharma Pty Ltd
QB	Bionime Australia Pty Limited
QH	Cortex Health Pty Ltd
QL	Amcla Pty Limited
RA	Ranbaxy Australia Pty Limited
RB	Bio Revive Pty Ltd
RC	Reckitt Benckiser (Australia) Pty Limited
RD	Roche Diagnostics Australia Pty Limited
RF	Arrow Pharma Pty Ltd
RI	Dr Reddy's Laboratories (Australia) Pty Ltd
RN	Ranbaxy Australia Pty Limited
RO	Roche Products Pty Ltd
RP	Roche Diabetes Care Australia Pty Limited
RW	Arrow Pharma Pty Ltd
RX	Servier Laboratories (Aust.) Pty Ltd
RZ	Dr Reddy's Laboratories (Australia) Pty Ltd
SA	SciGen (Australia) Pty Limited
SB	Nutricia Australia Pty Limited
SE	Servier Laboratories (Aust.) Pty Ltd
SG	Merck Serono Australia Pty Ltd
SI	Sigma Company Limited
SJ	Sharpe Laboratories Pty Ltd
SN	Smith & Nephew Pty Limited
SS	SSL Australia Pty Ltd
SW	sanofi-aventis Australia Pty Ltd
SY	Bayer Australia Ltd
SZ	Sandoz Pty Ltd
TB	Teva Pharma Australia Pty Limited
TD	STADA Pharmaceuticals Australia Pty Limited
TK	Takeda Pharmaceuticals Australia Pty Ltd
TL	Tolmar Australia Pty Ltd
TM	Technipro Marketing Pty Ltd
TS	Specialised Therapeutics Australia Pty Ltd
TW	Apotex Pty Ltd
TX	Apotex Pty Ltd
UA	Actavis Pty Ltd
UB	Merchantshub Networks (AustPacific) Pty Ltd
UC	UCB Australia Proprietary Limited
UH	uHealth Australia Pty Limited
UM	Unomedical Pty Ltd
UN	Unilever Australia Limited
VE	AbbVie Pty Ltd
VF	Vitaflo Australia Pty Limited
VI	ViiV Healthcare Pty Ltd
VL	Vifor Pharma Pty Limited
VR	Vertex Pharmaceuticals (Australia) Pty Ltd
WA	sanofi-aventis Australia Pty Ltd
WI	Wincot Pty Limited
XA	Pharmaxis Ltd
XH	MS Health Pty Ltd
XI	Alexion Pharmaceuticals Australasia Pty Ltd
XM	The Medicines Company (Australia) Pty Limited
YN	Mayne Pharma International Pty Ltd
YT	Mayne Products Pty Ltd
ZC	Anspec Pty Limited
ZD	Specialized Therapeutics Pty Ltd
ZI	Shire Australia Pty Limited
ZP	Medis Pharma Pty Ltd
ZX	Zenex Pharmaceuticals Pty Ltd

Generic/Proprietary Index