



Australian Government

Department of Health



Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 December 2015



Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 December 2015 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$6.93
	Dangerous drug fee	\$2.91
	Extemporaneously-prepared	\$8.97
	Allowable additional patient charge*	\$4.27
Additional Fees (for safety net prices):	Ready-prepared	\$1.17
	Extemporaneously-prepared	\$1.53
Patient Co-payments:	General	\$37.70
	Concessional	\$6.10
Safety Net Thresholds:	General	\$1453.90
	Concessional	\$366.00
Safety Net Card Issue Fee:		\$9.47

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

Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 December 2015. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

Prescriber Bag

Additions

Addition – Item

10016E **BENZTROPINE**, benztropine mesylate 2 mg/2 mL injection, 10 x 2 mL vials (*Benztropine Omega*)

General Pharmaceutical Benefits

Additions

Addition – Item

10565C **ACLIDINIUM + EFORMOTEROL**, acclidinium 340 microgram/actuation + eformoterol fumarate dihydrate 12 microgram/actuation inhalation: powder for, 60 actuations (*Brimica Genuair*)

10539Q **AXITINIB**, axitinib 1 mg tablet, 28 (*Inlyta*)

10572K **AXITINIB**, axitinib 1 mg tablet, 28 (*Inlyta*)

10540R **AXITINIB**, axitinib 5 mg tablet, 28 (*Inlyta*)

10556N **AXITINIB**, axitinib 5 mg tablet, 28 (*Inlyta*)

10013B **BENZTROPINE**, benztropine mesylate 2 mg/2 mL injection, 10 x 2 mL vials (*Benztropine Omega*)

10027R **BENZTROPINE**, benztropine mesylate 2 mg/2 mL injection, 10 x 2 mL vials (*Benztropine Omega*) (**Dental**)

10536M **BRINZOLAMIDE + BRIMONIDINE**, brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL (*Simbrinza* 1%/0.2%)

10547D **BRINZOLAMIDE + BRIMONIDINE**, brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL (*Simbrinza* 1%/0.2%) (**Optometrical**)

10538P **RIVASTIGMINE**, rivastigmine 13.3 mg/24 hours patch, 30 (*Exelon Patch 15*)

10541T **RIVASTIGMINE**, rivastigmine 13.3 mg/24 hours patch, 30 (*Exelon Patch 15*)

10551H **RIZATRIPTAN**, rizatriptan 10 mg tablet: orally disintegrating, 2 (*Rizatriptan AN ODT*)

10557P **TIOTROPIUM + OLODATEROL**, tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation: solution, 60 actuations (*Spolto Respimat*)

10555M **ZOLEDRONIC ACID**, zoledronic acid 5 mg/100 mL injection, 100 mL bag (*Ostira*)

10571J **ZOLEDRONIC ACID**, zoledronic acid 5 mg/100 mL injection, 100 mL bag (*Ostira*)

Addition – Brand

3138E	<i>Clindamylk, AF</i> – CLINDAMYCIN , clindamycin 150 mg capsule, 24
5057E	<i>Clindamylk, AF</i> – CLINDAMYCIN , clindamycin 150 mg capsule, 24 (Dental)
8729K	<i>GRANISETRON APOTEX, TX</i> – GRANISETRON , granisetron 3 mg/3 mL injection, 1 x 3 mL ampoule
8730L	<i>GRANISETRON APOTEX, TX</i> – GRANISETRON , granisetron 3 mg/3 mL injection, 1 x 3 mL ampoule
8534E	<i>Blooms the Chemist Lercanidipine, IB</i> – LERCANIDIPINE , lercanidipine hydrochloride 10 mg tablet, 28
8679T	<i>Blooms the Chemist Lercanidipine, IB</i> – LERCANIDIPINE , lercanidipine hydrochloride 20 mg tablet, 28
8043H	<i>Momasone, QA</i> – MOMETASONE , mometasone furoate 0.1% lotion, 30 mL
8508T	<i>Rabeprazole SUN, RN</i> – RABEPRAZOLE , rabeprazole sodium 20 mg tablet: enteric, 30
8509W	<i>Rabeprazole SUN, RN</i> – RABEPRAZOLE , rabeprazole sodium 20 mg tablet: enteric, 30
9313E	<i>Rizatriptan Wafers-10mg, FR</i> – RIZATRIPTAN , rizatriptan 10 mg wafer, 2
1849H	<i>Imigran, LN</i> – SUMATRIPTAN , sumatriptan 50 mg tablet, 4
9288W	<i>Osteovan, SZ</i> – ZOLEDRONIC ACID , zoledronic acid 5 mg/100 mL injection, 1 x 100 mL vial
9288W	<i>Zoledasta, TX</i> – ZOLEDRONIC ACID , zoledronic acid 5 mg/100 mL injection, 1 x 100 mL vial
9350D	<i>Osteovan, SZ</i> – ZOLEDRONIC ACID , zoledronic acid 5 mg/100 mL injection, 1 x 100 mL vial
9350D	<i>Zoledasta, TX</i> – ZOLEDRONIC ACID , zoledronic acid 5 mg/100 mL injection, 1 x 100 mL vial

Addition – Equivalence Indicator

9313E	<i>Maxalt, MK</i> – RIZATRIPTAN , rizatriptan 10 mg wafer, 2
9288W	<i>Aclasta, NV</i> – ZOLEDRONIC ACID , zoledronic acid 5 mg/100 mL injection, 1 x 100 mL vial
9350D	<i>Aclasta, NV</i> – ZOLEDRONIC ACID , zoledronic acid 5 mg/100 mL injection, 1 x 100 mL vial

Deletions

Deletion – Item

8613H	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE , amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 30 x 29 g sachets (<i>PKU Anamix Junior</i>)
9395L	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE , amino acid formula with vitamins and minerals without phenylalanine and tyrosine oral liquid: powder for, 30 x 29 g sachets (<i>TYR Anamix Junior</i>)
8745G	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE , amino acid formula with vitamins and minerals without valine, leucine and isoleucine oral liquid: powder for, 30 x 29 g sachets (<i>MSUD Anamix Junior</i>)

Deletion – Brand

2343H	<i>Amiodarone Actavis, EA</i> – AMIODARONE , amiodarone hydrochloride 200 mg tablet, 30
1259G	<i>Bisalax, AS</i> – BISACODYL , bisacodyl 5 mg tablet: enteric, 200 tablets
1147J	<i>GenRx Captopril, GX</i> – CAPTOPRIL , captopril 12.5 mg tablet, 90
1148K	<i>GenRx Captopril, GX</i> – CAPTOPRIL , captopril 25 mg tablet, 90
1149L	<i>GenRx Captopril, GX</i> – CAPTOPRIL , captopril 50 mg tablet, 90
2460L	<i>GenRx Cefaclor, GX</i> – CEFACLOR , cefaclor 125 mg/5 mL oral liquid: powder for, 100 mL
5046N	<i>GenRx Cefaclor, GX</i> – CEFACLOR , cefaclor 125 mg/5 mL oral liquid: powder for, 100 mL (Dental)
2461M	<i>GenRx Cefaclor, GX</i> – CEFACLOR , cefaclor 250 mg/5 mL oral liquid: powder for, 75 mL
5047P	<i>GenRx Cefaclor, GX</i> – CEFACLOR , cefaclor 250 mg/5 mL oral liquid: powder for, 75 mL (Dental)
1169M	<i>GenRx Cefaclor CD, GX</i> – CEFACLOR , cefaclor 375 mg tablet: modified release, 10
5045M	<i>GenRx Cefaclor CD, GX</i> – CEFACLOR , cefaclor 375 mg tablet: modified release, 10 (Dental)

1785Y	<i>Ceftriaxone Sandoz, SZ</i> – CEFTRIAXONE , ceftriaxone 2 g injection, 1 x 2 g vial
1370D	<i>Chem mart Enalapril, CH</i> – ENALAPRIL , enalapril maleate 5 mg tablet, 30
1370D	<i>GenRx Enalapril, GX</i> – ENALAPRIL , enalapril maleate 5 mg tablet, 30
1370D	<i>Terry White Chemists Enalapril, TW</i> – ENALAPRIL , enalapril maleate 5 mg tablet, 30
1368B	<i>Chem mart Enalapril, CH</i> – ENALAPRIL , enalapril maleate 10 mg tablet, 30
1368B	<i>GenRx Enalapril, GX</i> – ENALAPRIL , enalapril maleate 10 mg tablet, 30
1368B	<i>Terry White Chemists Enalapril, TW</i> – ENALAPRIL , enalapril maleate 10 mg tablet, 30
1369C	<i>Chem mart Enalapril, CH</i> – ENALAPRIL , enalapril maleate 20 mg tablet, 30
1369C	<i>GenRx Enalapril, GX</i> – ENALAPRIL , enalapril maleate 20 mg tablet, 30
1369C	<i>Terry White Chemists Enalapril, TW</i> – ENALAPRIL , enalapril maleate 20 mg tablet, 30
1182F	<i>GenRx Fosinopril, GX</i> – FOSINOPRIL , fosinopril sodium 10 mg tablet, 30
1183G	<i>GenRx Fosinopril, GX</i> – FOSINOPRIL , fosinopril sodium 20 mg tablet, 30
8400D	<i>APO-Fosinopril HCTZ 10/12.5, TX</i> – FOSINOPRIL + HYDROCHLOROTHIAZIDE , fosinopril sodium 10 mg + hydrochlorothiazide 12.5 mg tablet, 30
1900B	<i>Chem mart Moclobemide, CH</i> – MOCLOBEMIDE , moclobemide 150 mg tablet, 60
1900B	<i>Terry White Chemists Moclobemide, TW</i> – MOCLOBEMIDE , moclobemide 150 mg tablet, 60
8003F	<i>Chem mart Moclobemide, CH</i> – MOCLOBEMIDE , moclobemide 300 mg tablet, 60
8003F	<i>Terry White Chemists Moclobemide, TW</i> – MOCLOBEMIDE , moclobemide 300 mg tablet, 60
1754H	<i>Duratears, AQ</i> – PARAFFIN , paraffin 1 g/g eye ointment, 3.5 g
5523Q	<i>Duratears, AQ</i> – PARAFFIN , paraffin 1 g/g eye ointment, 3.5 g (Optometrical)
9217D	<i>Duratears, AQ</i> – PARAFFIN , paraffin 1 g/g eye ointment, 3.5 g
2043M	<i>Chem mart Sotalol, CH</i> – SOTALOL , sotalol hydrochloride 160 mg tablet, 60
2043M	<i>GenRx Sotalol, GX</i> – SOTALOL , sotalol hydrochloride 160 mg tablet, 60
2043M	<i>Terry White Chemists Sotalol, TW</i> – SOTALOL , sotalol hydrochloride 160 mg tablet, 60
8133C	<i>Chem mart Valaciclovir, CH</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 10
8133C	<i>Terry White Chemists Valaciclovir, TW</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 10

Deletion – Equivalence Indicator

8400D	<i>Monoplus 10/12.5, BQ</i> – FOSINOPRIL + HYDROCHLOROTHIAZIDE , fosinopril sodium 10 mg + hydrochlorothiazide 12.5 mg tablet, 30
1754H	<i>Poly Visc, IQ</i> – PARAFFIN , paraffin 1 g/g eye ointment, 3.5 g
5523Q	<i>Poly Visc, IQ</i> – PARAFFIN , paraffin 1 g/g eye ointment, 3.5 g (Optometrical)
9217D	<i>Poly Visc, IQ</i> – PARAFFIN , paraffin 1 g/g eye ointment, 3.5 g

Alterations

Changes to Restrictions

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

2019G	ACITRETIN , acitretin 10 mg capsule, 100 (<i>Acitretin Actavis, Neotigason, Novatin</i>)
2020H	ACITRETIN , acitretin 25 mg capsule, 100 (<i>Acitretin Actavis, Neotigason, Novatin</i>)
8459F	ALBENDAZOLE , albendazole 400 mg tablet: chewable, 60 (<i>Eskazole</i>)
8503M	ALBENDAZOLE , albendazole 200 mg tablet: chewable, 6 (<i>Zentel</i>)
9047E	ALBENDAZOLE , albendazole 200 mg tablet: chewable, 6 (<i>Zentel</i>)
2130D	ALPRAZOLAM , alprazolam 250 microgram tablet, 50 (<i>Alprax 0.25, Kalma 0.25</i>)
2131E	ALPRAZOLAM , alprazolam 500 microgram tablet, 50 (<i>Alprax 0.5, Kalma 0.5</i>)

2132F	ALPRAZOLAM , alprazolam 1 mg tablet, 50 (<i>Alprax 1, Chem mart Alprazolam, GenRx Alprazolam, Kalma 1, Terry White Chemists Alprazolam</i>)
8118G	ALPRAZOLAM , alprazolam 2 mg tablet, 50 (<i>Alprax 2, Chem mart Alprazolam, GenRx Alprazolam, Kalma 2, Terry White Chemists Alprazolam</i>)
8479G	AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE , amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine oral liquid: powder for, 400 g (<i>PKU Anamix infant</i>)
2347M	AMINO ACID FORMULA WITHOUT PHENYLALANINE , amino acid formula without phenylalanine oral liquid: powder for, 30 x 20 g sachets (<i>Phlexy-10 Drink Mix</i>)
8554F	AMINO ACID FORMULA WITHOUT PHENYLALANINE , amino acid formula without phenylalanine 500 mg capsule, 200 (<i>Phlexy-10</i>)
8678R	AMINO ACID FORMULA WITHOUT PHENYLALANINE , amino acid formula without phenylalanine 1 g tablet, 75 (<i>Phlexy-10</i>)
2343H	AMIODARONE , amiodarone hydrochloride 200 mg tablet, 30 (<i>, Amiodarone Sandoz, Aratac 200, Chem mart Amiodarone, Cordarone X 200, GenRx Amiodarone, Rithmik 200, Terry White Chemists Amiodarone</i>)
2344J	AMIODARONE , amiodarone hydrochloride 100 mg tablet, 30 (<i>Aratac 100, Cordarone X 100</i>)
8594H	AMISULPRIDE , amisulpride 100 mg tablet, 30 (<i>APO-Amisulpride, Amisulpride 100 Winthrop, Amisulpride Sandoz, Solian 100, Sulprix</i>)
8595J	AMISULPRIDE , amisulpride 200 mg tablet, 60 (<i>APO-Amisulpride, Amisulpride 200 Winthrop, Amisulpride Sandoz, Solian 200, Sulprix</i>)
8596K	AMISULPRIDE , amisulpride 400 mg tablet, 60 (<i>APO-Amisulpride, Amipride 400, Amisulpride 400 Winthrop, Amisulpride Sandoz, Solian 400, Sulprix</i>)
8736T	AMISULPRIDE , amisulpride 100 mg/mL oral liquid, 60 mL (<i>Solian Solution</i>)
9049G	AMLODIPINE + ATORVASTATIN , amlodipine 5 mg + atorvastatin 10 mg tablet, 30 (<i>APO-Amlodipine/Atorvastatin 5/10, Blooms the Chemist Amlodipine/Atorvastatin 5/10, Cadatin 5/10, Cadivast 5/10, Caduet 5/10, Chem mart Amlodipine/Atorvastatin 5/10, Terry White Chemists Amlodipine/Atorvastatin 5/10</i>)
9050H	AMLODIPINE + ATORVASTATIN , amlodipine 5 mg + atorvastatin 20 mg tablet, 30 (<i>APO-Amlodipine/Atorvastatin 5/20, Blooms the Chemist Amlodipine/Atorvastatin 5/20, Cadatin 5/20, Cadivast 5/20, Caduet 5/20, Chem mart Amlodipine/Atorvastatin 5/20, Terry White Chemists Amlodipine/Atorvastatin 5/20</i>)
9051J	AMLODIPINE + ATORVASTATIN , amlodipine 5 mg + atorvastatin 40 mg tablet, 30 (<i>APO-Amlodipine/Atorvastatin 5/40, Blooms the Chemist Amlodipine/Atorvastatin 5/40, Cadatin 5/40, Cadivast 5/40, Caduet 5/40, Chem mart Amlodipine/Atorvastatin 5/40, Terry White Chemists Amlodipine/Atorvastatin 5/40</i>)
9052K	AMLODIPINE + ATORVASTATIN , amlodipine 5 mg + atorvastatin 80 mg tablet, 30 (<i>APO-Amlodipine/Atorvastatin 5/80, Blooms the Chemist Amlodipine/Atorvastatin 5/80, Cadatin 5/80, Cadivast 5/80, Caduet 5/80, Chem mart Amlodipine/Atorvastatin 5/80, Terry White Chemists Amlodipine/Atorvastatin 5/80</i>)
9053L	AMLODIPINE + ATORVASTATIN , amlodipine 10 mg + atorvastatin 10 mg tablet, 30 (<i>APO-Amlodipine/Atorvastatin 10/10, Blooms the Chemist Amlodipine/Atorvastatin 10/10, Cadatin 10/10, Cadivast 10/10, Caduet 10/10, Chem mart Amlodipine/Atorvastatin 10/10, Terry White Chemists Amlodipine/Atorvastatin 10/10</i>)
9054M	AMLODIPINE + ATORVASTATIN , amlodipine 10 mg + atorvastatin 20 mg tablet, 30 (<i>APO-Amlodipine/Atorvastatin 10/20, Blooms the Chemist Amlodipine/Atorvastatin 10/20, Cadatin 10/20, Cadivast 10/20, Caduet 10/20, Chem mart Amlodipine/Atorvastatin 10/20, Terry White Chemists Amlodipine/Atorvastatin 10/20</i>)
9055N	AMLODIPINE + ATORVASTATIN , amlodipine 10 mg + atorvastatin 40 mg tablet, 30 (<i>APO-Amlodipine/Atorvastatin 10/40, Blooms the Chemist Amlodipine/Atorvastatin 10/40, Cadatin 10/40, Cadivast 10/40, Caduet 10/40, Chem mart Amlodipine/Atorvastatin 10/40, Terry White Chemists Amlodipine/Atorvastatin 10/40</i>)
9056P	AMLODIPINE + ATORVASTATIN , amlodipine 10 mg + atorvastatin 80 mg tablet, 30 (<i>APO-Amlodipine/Atorvastatin 10/80, Blooms the Chemist Amlodipine/Atorvastatin 10/80, Cadatin 10/80, Cadivast 10/80, Caduet 10/80, Chem mart Amlodipine/Atorvastatin 10/80, Terry White Chemists Amlodipine/Atorvastatin 10/80</i>)
5296R	ARTEMETHER + LUMEFANTRINE , artemether 20 mg + lumefantrine 120 mg tablet: dispersible, 18 (<i>Riamet 20mg/120mg Dispersible</i>)
9498X	ARTEMETHER + LUMEFANTRINE , artemether 20 mg + lumefantrine 120 mg tablet, 24 (<i>Riamet</i>)
5140M	ASENAPINE , asenapine 5 mg wafer: sublingual, 60 wafers (<i>Saphris</i>)
5141N	ASENAPINE , asenapine 10 mg wafer: sublingual, 60 wafers (<i>Saphris</i>)
8213G	ATORVASTATIN , atorvastatin 10 mg tablet, 30 (<i>APO-Atorvastatin, Atorvachol, Atorvastatin AN, Atorvastatin GH, Atorvastatin Pfizer, Atorvastatin SCP 10, Atorvastatin SZ, Atorvastatin Sandoz, Blooms the Chemist Atorvastatin, Chem mart Atorvastatin, Lipitor, Lorstat 10, Terry White Chemists Atorvastatin, Torvastat 10, Trovas</i>)

8214H	ATORVASTATIN , atorvastatin 20 mg tablet, 30 (APO-Atorvastatin, Atorvachol, Atorvastatin AN, Atorvastatin GH, Atorvastatin Pfizer, Atorvastatin SCP 20, Atorvastatin SZ, Atorvastatin Sandoz, Blooms the Chemist Atorvastatin, Chem mart Atorvastatin, Lipitor, Lorstat 20, Terry White Chemists Atorvastatin, Torvastat 20, Trovas)
8215J	ATORVASTATIN , atorvastatin 40 mg tablet, 30 (APO-Atorvastatin, Atorvachol, Atorvastatin AN, Atorvastatin GH, Atorvastatin Pfizer, Atorvastatin SCP 40, Atorvastatin SZ, Atorvastatin Sandoz, Blooms the Chemist Atorvastatin, Chem mart Atorvastatin, Lipitor, Lorstat 40, Terry White Chemists Atorvastatin, Torvastat 40, Trovas)
8521L	ATORVASTATIN , atorvastatin 80 mg tablet, 30 (APO-Atorvastatin, Atorvachol, Atorvastatin AN, Atorvastatin GH, Atorvastatin Pfizer, Atorvastatin SCP 80, Atorvastatin SZ, Atorvastatin Sandoz, Blooms the Chemist Atorvastatin, Chem mart Atorvastatin, Lipitor, Lorstat 80, Terry White Chemists Atorvastatin, Torvastat 80, Trovas)
9230T	ATORVASTATIN , atorvastatin 10 mg tablet, 30 (APO-Atorvastatin, Atorvachol, Atorvastatin AN, Atorvastatin GH, Atorvastatin Pfizer, Atorvastatin SCP 10, Atorvastatin SZ, Atorvastatin Sandoz, Blooms the Chemist Atorvastatin, Chem mart Atorvastatin, Lipitor, Lorstat 10, Terry White Chemists Atorvastatin, Torvastat 10, Trovas)
9231W	ATORVASTATIN , atorvastatin 20 mg tablet, 30 (APO-Atorvastatin, Atorvachol, Atorvastatin AN, Atorvastatin GH, Atorvastatin Pfizer, Atorvastatin SCP 20, Atorvastatin SZ, Atorvastatin Sandoz, Blooms the Chemist Atorvastatin, Chem mart Atorvastatin, Lipitor, Lorstat 20, Terry White Chemists Atorvastatin, Torvastat 20, Trovas)
9232X	ATORVASTATIN , atorvastatin 40 mg tablet, 30 (APO-Atorvastatin, Atorvachol, Atorvastatin AN, Atorvastatin GH, Atorvastatin Pfizer, Atorvastatin SCP 40, Atorvastatin SZ, Atorvastatin Sandoz, Blooms the Chemist Atorvastatin, Chem mart Atorvastatin, Lipitor, Lorstat 40, Terry White Chemists Atorvastatin, Torvastat 40, Trovas)
9233Y	ATORVASTATIN , atorvastatin 80 mg tablet, 30 (APO-Atorvastatin, Atorvachol, Atorvastatin AN, Atorvastatin GH, Atorvastatin Pfizer, Atorvastatin SCP 80, Atorvastatin SZ, Atorvastatin Sandoz, Blooms the Chemist Atorvastatin, Chem mart Atorvastatin, Lipitor, Lorstat 80, Terry White Chemists Atorvastatin, Torvastat 80, Trovas)
8300W	ATOVAQUONE , atovaquone 750 mg/5 mL oral liquid, 210 mL (Wellvone)
9439T	ATOVAQUONE + PROGUANIL , atovaquone 250 mg + proguanil hydrochloride 100 mg tablet, 12 (Malarone)
8200N	AZITHROMYCIN , azithromycin 500 mg tablet, 2 (APO-Azithromycin, Azithromycin Sandoz, Azithromycin-GA, Chem mart Azithromycin, Terry White Chemists Azithromycin, Zithromax, Zitrocin)
8201P	AZITHROMYCIN , azithromycin 200 mg/5 mL oral liquid: powder for, 15 mL (Zithromax)
8336R	AZITHROMYCIN , azithromycin 500 mg tablet, 2 (APO-Azithromycin, Azithromycin Sandoz, Azithromycin-GA, Chem mart Azithromycin, Terry White Chemists Azithromycin, Zithromax, Zitrocin)
1121B	BENZYDAMINE , benzydamine hydrochloride 0.15% mouthwash, 500 mL (Diffiam)
5032W	BENZYDAMINE , benzydamine hydrochloride 0.15% mouthwash, 500 mL (Diffiam)(Dental)
8094B	BICALUTAMIDE , bicalutamide 50 mg tablet, 28 (APO-Bicalutamide, Bicalox, Bicalutamide AN, Bicalutamide-GA, Calutex, Cosamide, Cosudex)
1258F	BISACODYL , bisacodyl 10 mg suppository, 12 (Petrus Bisacodyl Suppositories)
1259G	BISACODYL , bisacodyl 5 mg tablet: enteric, 200 tablets (Lax-Tab)
1260H	BISACODYL , bisacodyl 10 mg suppository, 10 (Dulcolax, Petrus Bisacodyl Suppositories)
1263L	BISACODYL , bisacodyl 10 mg/5 mL enema, 25 x 5 mL (Bisalax)
1208N	CIPROFLOXACIN , ciprofloxacin 250 mg tablet, 14 (APO-Ciprofloxacin, C-Flox 250, Ciprofloxacin Sandoz, Ciprofloxacin-DRLA, Ciprol 250, Ciproxin 250, GenRx Ciprofloxacin)
1209P	CIPROFLOXACIN , ciprofloxacin 500 mg tablet, 14 (APO-Ciprofloxacin, C-Flox 500, Cifran, Ciprofloxacin 500, Ciprofloxacin AN, Ciprofloxacin Sandoz, Ciprofloxacin-BW, Ciprofloxacin-DRLA, Ciprofloxacin-GA, Ciprol 500, Ciproxin 500, GenRx Ciprofloxacin, Loxip 500)
1210Q	CIPROFLOXACIN , ciprofloxacin 750 mg tablet, 14 (APO-Ciprofloxacin, C-Flox 750, Cifran, Ciprofloxacin 750, Ciprofloxacin AN, Ciprofloxacin Sandoz, Ciprofloxacin-BW, Ciprofloxacin-DRLA, Ciprofloxacin-GA, Ciprol 750, GenRx Ciprofloxacin, Loxip 750)
9192T	CLARITHROMYCIN , clarithromycin 250 mg/5 mL oral liquid: powder for, 50 mL (Klacid)
10011X	DAPAGLIFLOZIN , dapagliflozin 10 mg tablet, 28 (Forxiga)
10510E	DAPAGLIFLOZIN + METFORMIN , dapagliflozin 5 mg + metformin hydrochloride 1 g tablet: modified release, 56 (Xigduo XR 5/1000)
10515K	DAPAGLIFLOZIN + METFORMIN , dapagliflozin 10 mg + metformin hydrochloride 1 g tablet: modified release, 28 (Xigduo XR 10/1000)
10516L	DAPAGLIFLOZIN + METFORMIN , dapagliflozin 10 mg + metformin hydrochloride 500 mg tablet: modified release, 28 (Xigduo XR 10/500)
2784M	DEGARELIX , degarelix 80 mg injection [1 x 80 mg vial] (&) inert substance diluent [1 syringe], 1 pack (Firmagon 80mg)

2785N	DEGARELIX , degarelix 120 mg injection [2 x 120 mg vials] (&) inert substance diluent [2 syringes], 1 pack (<i>Firmagon 120mg</i>)
8738X	ESOMEPRAZOLE (&) CLARITHROMYCIN (&) AMOXYCILLIN , esomeprazole 20 mg tablet: enteric [14 tablets] (&) clarithromycin 500 mg tablet [14 tablets] (&) amoxycillin 500 mg capsule [28 capsules], 1 pack (<i>Nexium Hp7</i>)
1525G	FLUCLOXACILLIN , flucloxacillin 1 g injection, 5 x 1 g vials (<i>Flubiclox, Flucil, Hospira Pty Limited</i>)
5095E	FLUCLOXACILLIN , flucloxacillin 1 g injection, 5 x 1 g vials (<i>Flubiclox, Flucil, Hospira Pty Limited</i>)(Dental)
1471K	FLUCONAZOLE , fluconazole 50 mg capsule, 28 (<i>Diflucan, Dizole 50, Fluconazole Sandoz, Ozole</i>)
1472L	FLUCONAZOLE , fluconazole 100 mg capsule, 28 (<i>Diflucan, Dizole 100, Fluconazole Sandoz, Ozole</i>)
1473M	FLUCONAZOLE , fluconazole 100 mg/50 mL injection, 1 x 50 mL vial (<i>Fluconazole Hexal, Fluconazole Sandoz</i>)
1474N	FLUCONAZOLE , fluconazole 200 mg/100 mL injection, 1 x 100 mL vial (<i>Fluconazole Alphapharm, Fluconazole Hexal, Fluconazole Sandoz</i>)
1475P	FLUCONAZOLE , fluconazole 200 mg capsule, 28 (<i>APO-Fluconazole, Diflucan, Dizole 200, Fluconazole Sandoz, Fluzole 200, Ozole</i>)
1757L	FLUCONAZOLE , fluconazole 400 mg/200 mL injection, 1 x 200 mL bag (<i>Fluconazole Alphapharm</i>)
5446P	FLUCONAZOLE , fluconazole 50 mg/5 mL oral liquid: powder for, 35 mL (<i>Diflucan</i>)
1417N	FLUTAMIDE , flutamide 250 mg tablet, 100 (<i>Flutamin</i>)
8775W	FONDAPARINUX , FONDAPARINUX SODIUM Injection 2.5 mg in 0.5 mL single dose pre-filled syringe, 2 (<i>Arixtra</i>)
2555L	GLYCEROL , glycerol 700 mg suppository, 12 (<i>Petrus Pharmaceuticals Pty Ltd</i>)
2556M	GLYCEROL , glycerol 1.4 g suppository, 12 (<i>Petrus Pharmaceuticals Pty Ltd</i>)
2557N	GLYCEROL , glycerol 2.8 g suppository, 12 (<i>Petrus Pharmaceuticals Pty Ltd</i>)
2446R	IDARUBICIN , idarubicin hydrochloride 5 mg capsule, 1 (<i>Zavedos</i>)
2448W	IDARUBICIN , idarubicin hydrochloride 10 mg capsule, 1 (<i>Zavedos</i>)
10156M	INDACATEROL + GLYCOPYRRONIUM , indacaterol 110 microgram + glycopyrronium 50 microgram inhalation: powder for, 30 capsules (<i>ultibro breezhale 110/50</i>)
8196J	ITRACONAZOLE , itraconazole 100 mg capsule, 60 (<i>Sporanox</i>)
2240X	LANSOPRAZOLE , lansoprazole 30 mg capsule: enteric, 28 (<i>APO-Lansoprazole, Lanzopran, Zopral</i>)
2241Y	LANSOPRAZOLE , lansoprazole 30 mg capsule: enteric, 28 (<i>APO-Lansoprazole, Lanzopran, Zopral</i>)
8198L	LANSOPRAZOLE , lansoprazole 15 mg capsule: enteric, 30 (<i>Zopral</i>)
9331D	LANSOPRAZOLE , lansoprazole 15 mg tablet: orally disintegrating, 28 tablets (<i>APO-Lansoprazole ODT, Lansoprazole ODT GH, Zopral ODT, Zoton FasTabs</i>)
9477T	LANSOPRAZOLE , lansoprazole 30 mg tablet: orally disintegrating, 28 tablets (<i>APO-Lansoprazole ODT, Lansoprazole ODT GH, Zopral ODT, Zoton FasTabs</i>)
9478W	LANSOPRAZOLE , lansoprazole 30 mg tablet: orally disintegrating, 28 tablets (<i>APO-Lansoprazole ODT, Lansoprazole ODT GH, Zopral ODT, Zoton FasTabs</i>)
5449T	LEFLUNOMIDE , leflunomide 10 mg tablet, 30 (<i>Arabloc, Arava, Leflunomide Sandoz</i>)
5450W	LEFLUNOMIDE , leflunomide 20 mg tablet, 30 (<i>Arabloc, Arava, Leflunomide Sandoz</i>)
8374R	LEFLUNOMIDE , leflunomide 10 mg tablet, 30 (<i>APO-Leflunomide, Arabloc, Arava, Leflunomide AN, Leflunomide GH, Leflunomide Sandoz, Leflunomide-GA, Lunava 10</i>)
8375T	LEFLUNOMIDE , leflunomide 20 mg tablet, 30 (<i>APO-Leflunomide, Arabloc, Arava, Leflunomide AN, Leflunomide GH, Leflunomide Sandoz, Leflunomide-GA, Lunava 20</i>)
10256T	LEUPRORELIN , leuprorelin acetate 30 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack (<i>Lucrin Depot Paediatric 30 mg PDS</i>)
8707G	LEUPRORELIN , leuprorelin acetate 7.5 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack (<i>Eligard 1 month</i>)
8708H	LEUPRORELIN , leuprorelin acetate 22.5 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack (<i>Eligard 3 month</i>)
8709J	LEUPRORELIN , leuprorelin acetate 30 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack (<i>Eligard 4 month</i>)
8859G	LEUPRORELIN , leuprorelin acetate 45 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack (<i>Eligard 6 month</i>)

8875D	LEUPRORELIN , leuporelin acetate 7.5 mg injection: modified release [1 x 7.5 mg syringe] (&) inert substance diluent [1 x 2 mL syringe], 1 pack (<i>Lucrin Depot 7.5mg PDS</i>)
8876E	LEUPRORELIN , leuporelin acetate 22.5 mg injection: modified release [1 x 22.5 mg syringe] (&) inert substance diluent [1 x 2 mL syringe], 1 pack (<i>Lucrin Depot 3 Month PDS</i>)
8877F	LEUPRORELIN , leuporelin acetate 30 mg injection: modified release [1 x 30 mg syringe] (&) inert substance diluent [1 x 2 mL syringe], 1 pack (<i>Lucrin Depot 4 Month PDS</i>)
2316X	MEDROXYPROGESTERONE , medroxyprogesterone acetate 200 mg tablet, 60 (<i>Provera</i>)
2725K	MEDROXYPROGESTERONE , medroxyprogesterone acetate 100 mg tablet, 100 (<i>Provera</i>)
2727M	MEDROXYPROGESTERONE , medroxyprogesterone acetate 250 mg tablet, 60 (<i>Provera</i>)
2728N	MEDROXYPROGESTERONE , medroxyprogesterone acetate 500 mg tablet, 30 (<i>Provera</i>)
1623K	METHOTREXATE , methotrexate 10 mg tablet, 50 (<i>Methoblastin</i>)
1621H	METRONIDAZOLE , metronidazole 400 mg tablet, 21 (<i>Flagyl, Metrogyl 400, Metronide 400</i>)
5155H	METRONIDAZOLE , metronidazole 400 mg tablet, 21 (<i>Flagyl, Metrogyl 400, Metronide 400</i>)(Dental)
8131Y	NILUTAMIDE , nilutamide 150 mg tablet, 30 (<i>Anandron</i>)
2732T	NITRAZEPAM , nitrazepam 5 mg tablet, 25 (<i>Alodorm, Mogadon</i>)
3010K	NORFLOXACIN , norfloxacin 400 mg tablet, 14 (<i>GenRx Norfloxacin, Norfloxacin Sandoz, Norfloxacin-GA, Nufloxib, Roxin</i>)
8332M	OMEPRAZOLE , omeprazole 10 mg tablet: enteric, 30 tablets (<i>Losec Tablets</i>)
1594X	ONDANSETRON , ondansetron 4 mg tablet, 10 (<i>APO-Ondansetron, Ondansetron AN, Ondansetron SZ, Ondansetron-DRLA, Ondaz, Onsetron 4, Zilfojim 4, Zofran</i>)
1595Y	ONDANSETRON , ondansetron 8 mg tablet, 10 (<i>APO-Ondansetron, Ondansetron AN, Ondansetron SZ, Ondansetron-DRLA, Ondaz, Onsetron 8, Zilfojim 8, Zofran</i>)
1596B	ONDANSETRON , ondansetron 4 mg/2 mL injection, 1 x 2 mL ampoule (<i>Ondansetron Alphapharm, Ondansetron Kabi, Ondansetron-Claris, Onsetron</i>)
1597C	ONDANSETRON , ondansetron 8 mg/4 mL injection, 1 x 4 mL ampoule (<i>Ondansetron Alphapharm, Ondansetron Kabi, Ondansetron-Claris, Onsetron</i>)
5470X	ONDANSETRON , ONDANSETRON Tablet (orally disintegrating) 4 mg, 4 (<i>Ondansetron AN ODT, Ondansetron ODT-DRLA, Ondansetron SZ ODT, Onsetron ODT 4</i>)
5471Y	ONDANSETRON , ONDANSETRON Tablet (orally disintegrating) 8 mg, 4 (<i>Ondansetron AN ODT, Ondansetron ODT-DRLA, Ondansetron SZ ODT, Onsetron ODT 8</i>)
5472B	ONDANSETRON , ONDANSETRON Tablet (orally disintegrating) 4 mg, 10 (<i>Ondansetron AN ODT, Ondansetron ODT-DRLA, Ondansetron SZ ODT, Onsetron ODT 4, Zilfojim ODT 4</i>)
5473C	ONDANSETRON , ONDANSETRON Tablet (orally disintegrating) 8 mg, 10 (<i>Ondansetron AN ODT, Ondansetron ODT-DRLA, Ondansetron SZ ODT, Onsetron ODT 8, Zilfojim ODT 8</i>)
8224W	ONDANSETRON , ondansetron 4 mg tablet, 4 (<i>APO-Ondansetron, Ondansetron AN, Ondansetron SZ, Ondansetron-DRLA, Ondaz, Onsetron 4, Zofran</i>)
8225X	ONDANSETRON , ondansetron 8 mg tablet, 4 (<i>APO-Ondansetron, Ondansetron AN, Ondansetron SZ, Ondansetron-DRLA, Ondaz, Onsetron 8, Zofran</i>)
8226Y	ONDANSETRON , ondansetron 4 mg/2 mL injection, 1 x 2 mL ampoule (<i>Ondansetron Alphapharm, Ondansetron Kabi, Ondansetron-Claris, Onsetron</i>)
8227B	ONDANSETRON , ondansetron 8 mg/4 mL injection, 1 x 4 mL ampoule (<i>Ondansetron Alphapharm, Ondansetron Kabi, Ondansetron-Claris, Onsetron</i>)
8233H	ONDANSETRON , ondansetron 4 mg/5 mL oral liquid, 50 mL (<i>Zofran syrup 50 mL</i>)
8410P	ONDANSETRON , ondansetron 4 mg wafer, 4 (<i>Ondaz Zydis, Zofran Zydis</i>)
8411Q	ONDANSETRON , ondansetron 8 mg wafer, 4 (<i>Ondaz Zydis, Zofran Zydis</i>)
8412R	ONDANSETRON , ondansetron 4 mg wafer, 10 (<i>Ondaz Zydis, Zofran Zydis</i>)
8413T	ONDANSETRON , ondansetron 8 mg wafer, 10 (<i>Ondaz Zydis, Zofran Zydis</i>)
9441X	ONDANSETRON , ondansetron 4 mg/5 mL oral liquid, 50 mL (<i>Zofran syrup 50 mL</i>)
5295Q	PALONOSETRON , palonosetron 250 microgram/5 mL injection, 1 x 5 mL vial (<i>Aloxi</i>)

5453B	PANCREATIC EXTRACT , pancreatic extract 5000 international units/100 mg granules: enteric-coated, 20 g (<i>Creon Micro</i>)
5454C	PANCREATIC EXTRACT , pancreatic extract 5000 international units/100 mg granules: enteric-coated, 20 g (<i>Creon Micro</i>)
8020D	PANCREATIC EXTRACT , pancreatic extract 10 000 international units capsule: modified release, 100 capsules (<i>Creon 10,000</i>)
8021E	PANCREATIC EXTRACT , pancreatic extract 25 000 international units capsule: modified release, 100 capsules (<i>Creon 25,000</i>)
9226N	PANCREATIC EXTRACT , pancreatic extract 10 000 international units capsule: modified release, 100 capsules (<i>Creon 10,000</i>)
9227P	PANCREATIC EXTRACT , pancreatic extract 25 000 international units capsule: modified release, 100 capsules (<i>Creon 25,000</i>)
9412J	PANCREATIC EXTRACT , pancreatic extract 40 000 international units capsule: modified release, 100 capsules (<i>Creon 40,000</i>)
9413K	PANCREATIC EXTRACT , pancreatic extract 40 000 international units capsule: modified release, 100 capsules (<i>Creon 40,000</i>)
8366H	PANCRELIPASE , pancrelipase 25 000 units capsule, 100 (<i>Panzytrat 25000</i>)
9229R	PANCRELIPASE , pancrelipase 25 000 units capsule, 100 (<i>Panzytrat 25000</i>)
9217D	PARAFFIN , paraffin 1 g/g eye ointment, 3.5 g (, <i>Poly Visc</i>)
1703P	PHENOXYMETHYLPENICILLIN , phenoxymethylpenicillin 250 mg tablet, 25 (<i>Abbocillin-VK Filmstab</i>)
1705R	PHENOXYMETHYLPENICILLIN , phenoxymethylpenicillin 250 mg capsule, 50 (<i>Cilicaine VK, Cilopen VK, LPV</i>)
9360P	POSACONAZOLE , posaconazole 40 mg/mL oral liquid, 105 mL (<i>Noxafil</i>)
9447F	PRAZIQUANTEL , praziquantel 600 mg tablet, 8 (<i>Biltricide</i>)
5458G	QUETIAPINE , quetiapine 150 mg tablet: modified release, 60 tablets (<i>Seroquel XR</i>)
8457D	QUETIAPINE , quetiapine 100 mg tablet, 90 (<i>APO-Quetiapine, Chem mart Quetiapine, Delucon 100, Kaptan, Pharmacor Quetiapine 100, Pharmacy Choice Quetiapine, Quetia 100, Quetiaccord, Quetiapine AN, Quetiapine Actavis 100, Quetiapine GH 100, Quetiapine RBX, Quetiapine Sandoz, Quetiapine-DRLA, Quetiapine-GA, Seronia 100, Seroquel, Syquet, Terry White Chemists Quetiapine</i>)
8458E	QUETIAPINE , quetiapine 200 mg tablet, 60 (<i>APO-Quetiapine, Chem mart Quetiapine, Delucon 200, Kaptan, Pharmacor Quetiapine 200, Pharmacy Choice Quetiapine, Quetia 200, Quetiaccord, Quetiapine AN, Quetiapine Actavis 200, Quetiapine GH 200, Quetiapine RBX, Quetiapine Sandoz, Quetiapine-DRLA, Quetiapine-GA, Seronia 200, Seroquel, Syquet, Terry White Chemists Quetiapine</i>)
8580N	QUETIAPINE , quetiapine 300 mg tablet, 60 (<i>APO-Quetiapine, Chem mart Quetiapine, Delucon 300, Kaptan, Pharmacor Quetiapine 300, Pharmacy Choice Quetiapine, Quetia 300, Quetiaccord, Quetiapine AN, Quetiapine Actavis 300, Quetiapine GH 300, Quetiapine RBX, Quetiapine Sandoz, Quetiapine-DRLA, Quetiapine-GA, Seronia 300, Seroquel, Syquet, Terry White Chemists Quetiapine</i>)
9202H	QUETIAPINE , quetiapine 50 mg tablet: modified release, 60 tablets (<i>Seroquel XR</i>)
9203J	QUETIAPINE , quetiapine 200 mg tablet: modified release, 60 tablets (<i>Seroquel XR</i>)
9204K	QUETIAPINE , quetiapine 300 mg tablet: modified release, 60 tablets (<i>Seroquel XR</i>)
9205L	QUETIAPINE , quetiapine 400 mg tablet: modified release, 60 tablets (<i>Seroquel XR</i>)
1975Y	QUININE , quinine sulfate 300 mg tablet, 50 (<i>Quinate</i>)
8507R	RABEPRAZOLE , rabeprazole sodium 10 mg tablet: enteric, 28 (<i>APO-Rabeprazole, Chem mart Rabeprazole, Parbezol, Pariet, Parzol 10, Prabez, Rabeprazole AN, Rabeprazole Sandoz, Rabeprazole generichealth, Rabeprazole-DRLA, Rabeprazole-GA, Razit 10, Terry White Chemists Rabeprazole</i>)
8508T	RABEPRAZOLE , rabeprazole sodium 20 mg tablet: enteric, 30 (<i>APO-Rabeprazole, Chem mart Rabeprazole, Parbezol, Pariet, Parzol 20, Prabez, Rabeprazole AN, Rabeprazole Actavis 20, Rabeprazole SUN, Rabeprazole Sandoz, Rabeprazole generichealth, Rabeprazole-DRLA, Razit 20, Terry White Chemists Rabeprazole, Zabep</i>)
8509W	RABEPRAZOLE , rabeprazole sodium 20 mg tablet: enteric, 30 (<i>APO-Rabeprazole, Chem mart Rabeprazole, Parbezol, Pariet, Parzol 20, Prabez, Rabeprazole AN, Rabeprazole Actavis 20, Rabeprazole SUN, Rabeprazole Sandoz, Rabeprazole generichealth, Rabeprazole-DRLA, Razit 20, Terry White Chemists Rabeprazole, Zabep</i>)
8253J	RETEPLASE , reteplase 10 units (17.4 mg) injection [2 x 10 units vials] (&) inert substance diluent [2 x 10 mL syringes], 1 pack (<i>Rapilysin 10 U</i>)

1104D	RHAMNUS FRANGULA + STERCULIA , rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g (<i>Normacol Plus</i>)
9313E	RIZATRIPTAN , rizatriptan 10 mg wafer, 2 (<i>Maxalt, Rizatriptan Wafers-10mg</i>)
10128C	SAXAGLIPTIN , saxagliptin 2.5 mg tablet, 28 (<i>Onglyza</i>)
8983T	SAXAGLIPTIN , saxagliptin 5 mg tablet, 28 (<i>Onglyza</i>)
10048W	SAXAGLIPTIN + METFORMIN , saxagliptin 2.5 mg + metformin hydrochloride 1 g tablet: modified release, 56 (<i>Kombiglyze XR 2.5/1000</i>)
10051B	SAXAGLIPTIN + METFORMIN , saxagliptin 5 mg + metformin hydrochloride 1 g tablet: modified release, 28 (<i>Kombiglyze XR 5/1000</i>)
10055F	SAXAGLIPTIN + METFORMIN , saxagliptin 5 mg + metformin hydrochloride 500 mg tablet: modified release, 28 (<i>Kombiglyze XR 5/500</i>)
9180E	SITAGLIPTIN , sitagliptin 25 mg tablet, 28 (<i>Januvia</i>)
9181F	SITAGLIPTIN , sitagliptin 50 mg tablet, 28 (<i>Januvia</i>)
9182G	SITAGLIPTIN , sitagliptin 100 mg tablet, 28 (<i>Januvia</i>)
10089B	SITAGLIPTIN + METFORMIN , sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28 (<i>Janumet XR</i>)
10090C	SITAGLIPTIN + METFORMIN , sitagliptin 50 mg + metformin hydrochloride 1 g tablet: modified release, 56 (<i>Janumet XR</i>)
9449H	SITAGLIPTIN + METFORMIN , sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56 (<i>Janumet</i>)
9450J	SITAGLIPTIN + METFORMIN , sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56 (<i>Janumet</i>)
9451K	SITAGLIPTIN + METFORMIN , sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56 (<i>Janumet</i>)
2091C	SORBITOL + CITRATE + LAURYL SULFOACETATE SODIUM , sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL (<i>Micolette, Microlax</i>)
2043M	SOTALOL , sotalol hydrochloride 160 mg tablet, 60 (<i>APO-Sotalol, Cardol, Solavert, Sotacor, Sotalol Sandoz,)</i>
8398B	SOTALOL , sotalol hydrochloride 80 mg tablet, 60 (<i>APO-Sotalol, GenRx Sotalol, Solavert, Sotacor, Sotalol Sandoz</i>)
1880Y	TAMOXIFEN , tamoxifen 20 mg tablet, 30 (<i>Nolvadex-D</i>)
2109B	TAMOXIFEN , tamoxifen 10 mg tablet, 60 (<i>Genox 10</i>)
2110C	TAMOXIFEN , tamoxifen 20 mg tablet, 60 (<i>GenRx Tamoxifen, Genox 20, Tamosin, Tamoxen 20 mg, Tamoxifen Sandoz</i>)
2088X	TEMAZEPAM , temazepam 10 mg tablet, 25 (<i>APO-Temazepam, Normison, Temaze, Temtabs</i>)
2089Y	TEMAZEPAM , temazepam 10 mg tablet, 25 (<i>APO-Temazepam, Normison, Temaze, Temtabs</i>)
8526R	TENECTEPLASE , tenecteplase 8000 international units (40 mg) injection [1 x 40 mg vial] (&) inert substance diluent [1 x 8 mL syringe], 1 pack (<i>Metalyse</i>)
8527T	TENECTEPLASE , tenecteplase 10 000 international units (50 mg) injection [1 x 50 mg vial] (&) inert substance diluent [1 x 10 mL syringe], 1 pack (<i>Metalyse</i>)
1418P	TICAGRELOR , TICAGRELOR Tablet 90 mg, 56 (<i>Brilinta</i>)
8350L	TIROFIBAN , tirofiban 12.5 mg/50 mL injection, 1 x 50 mL vial (<i>Aggrastat, Tirofiban AC</i>)
9308X	TRIGLYCERIDES LONG CHAIN WITH GLUCOSE POLYMER , triglycerides long chain with glucose polymer oral liquid, 18 x 250 mL cans (<i>ProZero</i>)
9309Y	TRIGLYCERIDES LONG CHAIN WITH GLUCOSE POLYMER , triglycerides long chain with glucose polymer oral liquid, 6 x 1000 mL bottles (<i>ProZero</i>)
3128P	TRIGLYCERIDES MEDIUM CHAIN , triglycerides medium chain oil: oral, 500 mL (<i>MCT Oil</i>)
9327X	TRIGLYCERIDES MEDIUM CHAIN , triglycerides medium chain oral liquid, 1 x 250 mL bottle (<i>Liquigen</i>)
3136C	TRIGLYCERIDES MEDIUM CHAIN AND LONG CHAIN WITH GLUCOSE POLYMER , triglycerides medium chain and long chain with glucose polymer oral liquid: powder for, 400 g (<i>Duocal</i>)
9383W	TRIGLYCERIDES MEDIUM CHAIN FORMULA , triglycerides medium chain formula oral liquid: powder for, 30 x 16 g sachets (<i>MCT Pro-Cal</i>)
5297T	TRIPTORELIN , triptorelin 22.5 mg injection [1 x 22.5 mg vial] (&) inert substance diluent [1 x 2 mL ampoule], 1 pack (<i>Diphereline</i>)

9378N	TRIPTORELIN , triptorelin 3.75 mg injection [1 x 3.75 mg vial] (& inert substance diluent [1 x 2 mL ampoule], 1 pack (<i>Diphereline</i>)
9379P	TRIPTORELIN , triptorelin 11.25 mg injection [1 x 11.25 mg vial] (& inert substance diluent [1 x 2 mL ampoule], 1 pack (<i>Diphereline</i>)
2746M	TROPISETRON , tropisetron 5 mg/5 mL injection, 1 x 5 mL ampoule (<i>Tropisetron-AFT</i>)
10188F	UMECLIDINIUM + VILANTEROL , umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation inhalation: powder for, 30 actuations (<i>Anoro Ellipta 62.5/25</i>)
8448P	URSODEOXYCHOLIC ACID , ursodeoxycholic acid 250 mg capsule, 100 (<i>Ursofalk, Ursosan</i>)
2269K	VANCOMYCIN , vancomycin 1 g injection, 1 x 1 g vial (<i>Hospira Pty Limited, Vancomycin Alphapharm, Vancomycin Sandoz, Vycin IV</i>)
2270L	VANCOMYCIN , vancomycin 1 g injection, 1 x 1 g vial (<i>Hospira Pty Limited, Vancomycin Alphapharm, Vancomycin Sandoz, Vycin IV</i>)
3113W	VANCOMYCIN , vancomycin 125 mg capsule, 20 (<i>Vancocin</i>)
3114X	VANCOMYCIN , vancomycin 250 mg capsule, 20 (<i>Vancocin</i>)
3130R	VANCOMYCIN , vancomycin 500 mg injection, 1 x 500 mg vial (<i>Hospira Pty Limited, Vancocin CP, Vancomycin Alphapharm, Vancomycin Sandoz</i>)
3131T	VANCOMYCIN , vancomycin 500 mg injection, 1 x 500 mg vial (<i>Hospira Pty Limited, Vancocin CP, Vancomycin Alphapharm, Vancomycin Sandoz</i>)
3323X	VANCOMYCIN , vancomycin 500 mg injection, 1 x 500 mg vial (<i>Hospira Pty Limited, Vancocin CP, Vancomycin Alphapharm, Vancomycin Sandoz</i>)(Dental)
5083M	VANCOMYCIN , vancomycin 1 g injection, 1 x 1 g vial (<i>Hospira Pty Limited, Vancomycin Alphapharm, Vancomycin Sandoz, Vycin IV</i>)(Dental)
8301X	VENLAFAXINE , venlafaxine 75 mg capsule: modified release, 28 capsules (<i>APO-Venlafaxine XR, Altven, Blooms the Chemist Venlafaxine XR, Chem mart Venlafaxine XR, Efexor-XR, Elaxine SR 75, Enlafax-XR, Terry White Chemists Venlafaxine XR, Venla RBX, Venlafaxine AN SR, Venlafaxine Actavis XR, Venlafaxine SR SCP 75, Venlafaxine Sandoz XR, Venlafaxine generichealth XR, Venlexor XR</i>)
8302Y	VENLAFAXINE , venlafaxine 150 mg capsule: modified release, 28 capsules (<i>APO-Venlafaxine XR, Altven, Blooms the Chemist Venlafaxine XR, Chem mart Venlafaxine XR, Efexor-XR, Elaxine SR 150, Enlafax-XR, Terry White Chemists Venlafaxine XR, Venla RBX, Venlafaxine AN SR, Venlafaxine Actavis XR, Venlafaxine SR SCP 150, Venlafaxine Sandoz XR, Venlafaxine generichealth XR, Venlexor XR</i>)
8868R	VENLAFAXINE , venlafaxine 37.5 mg capsule: modified release, 28 capsules (<i>Altven, Efexor-XR, Elaxine SR 37.5, Venlafaxine AN SR, Venlafaxine Actavis XR</i>)
9363T	VORICONAZOLE , voriconazole 50 mg tablet, 56 (<i>Vfend</i>)
9364W	VORICONAZOLE , voriconazole 200 mg tablet, 56 (<i>Vfend</i>)
9452L	VORICONAZOLE , voriconazole 40 mg/mL oral liquid: powder for, 70 mL (<i>Vfend</i>)
9070J	ZIPRASIDONE , ziprasidone 20 mg capsule, 60 (<i>APO-Ziprasidone, Zeldox</i>)
9071K	ZIPRASIDONE , ziprasidone 40 mg capsule, 60 (<i>APO-Ziprasidone, Zeldox</i>)
9072L	ZIPRASIDONE , ziprasidone 60 mg capsule, 60 (<i>APO-Ziprasidone, Zeldox</i>)
9073M	ZIPRASIDONE , ziprasidone 80 mg capsule, 60 (<i>APO-Ziprasidone, Zeldox</i>)
9288W	ZOLEDRONIC ACID , zoledronic acid 5 mg/100 mL injection, 1 x 100 mL vial (<i>Aclasta, Osteovan, Zoledasta</i>)
9350D	ZOLEDRONIC ACID , zoledronic acid 5 mg/100 mL injection, 1 x 100 mL vial (<i>Aclasta, Osteovan, Zoledasta</i>)

Alteration – Manufacturer Code

		From	To
2390T	<i>Ibimicyn</i> – AMPICILLIN , ampicillin 500 mg injection, 5 x 500 mg vials	EA	JU
3313J	<i>Ibimicyn</i> – AMPICILLIN , ampicillin 500 mg injection, 5 x 500 mg vials (Dental)	EA	JU
2977Q	<i>Ibimicyn</i> – AMPICILLIN , ampicillin 1 g injection, 5 x 1 g vials	EA	JU
3314K	<i>Ibimicyn</i> – AMPICILLIN , ampicillin 1 g injection, 5 x 1 g vials (Dental)	EA	JU
1524F	<i>Flubiclox</i> – FLUCLOXACILLIN , flucloxacillin 500 mg injection, 5 x 500 mg vials	EA	JU
5094D	<i>Flubiclox</i> – FLUCLOXACILLIN , flucloxacillin 500 mg injection, 5 x 500 mg vials (Dental)	EA	JU
1525G	<i>Flubiclox</i> – FLUCLOXACILLIN , flucloxacillin 1 g injection, 5 x 1 g vials	EA	JU

5095E	<i>Flubiclox</i> – FLUCLOXACILLIN , flucloxacillin 1 g injection, 5 x 1 g vials (Dental)	EA	JU
2591J	<i>Oratane</i> – ISOTRETINOIN , isotretinoin 10 mg capsule, 60	GN	AG
2592K	<i>Oratane</i> – ISOTRETINOIN , isotretinoin 20 mg capsule, 60	GN	AG
2549E	<i>Oratane</i> – ISOTRETINOIN , isotretinoin 40 mg capsule, 30	GN	AG
9454N	<i>Oxytrol</i> – OXYBUTYNIN , oxybutynin 3.9 mg/24 hours patch, 8	GN	AG
8460G	<i>Androderm</i> – TESTOSTERONE , testosterone 2.5 mg/24 hours patch, 60	GN	AG
8619P	<i>Androderm</i> – TESTOSTERONE , testosterone 5 mg/24 hours patch, 30	GN	AG
8350L	<i>Tiروفiban AC</i> – TIROFIBAN , tirofiban 12.5 mg/50 mL injection, 1 x 50 mL vial	GN	JO

Advance Notices

1 January 2016

Deletion – Brand

10002K	<i>Atozet Composite Pack, MK</i> – ATORVASTATIN (&) EZETIMIBE , atorvastatin 10 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack
10006P	<i>Atozet Composite Pack, MK</i> – ATORVASTATIN (&) EZETIMIBE , atorvastatin 80 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack
2821L	<i>Atozet Composite Pack, MK</i> – ATORVASTATIN (&) EZETIMIBE , atorvastatin 40 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack
2874G	<i>Atozet Composite Pack, MK</i> – ATORVASTATIN (&) EZETIMIBE , atorvastatin 20 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack
8361C	<i>Xeloda, RO</i> – CAPECITABINE , capecitabine 150 mg tablet, 60
1086E	<i>Cefotaxime Sandoz, SZ</i> – CEFOTAXIME , cefotaxime 2 g injection, 1 x 2 g vial
5049R	<i>Cefotaxime Sandoz, SZ</i> – CEFOTAXIME , cefotaxime 2 g injection, 1 x 2 g vial (Dental)
5479J	<i>Cefazolin Sandoz, SZ</i> – CEPHAZOLIN , cephazolin 2 g injection, 1 x 2 g vial
9326W	<i>Cefazolin Sandoz, SZ</i> – CEPHAZOLIN , cephazolin 2 g injection, 1 x 2 g vial
1171P	<i>Chlorsig, QA</i> – CHLORAMPHENICOL , chloramphenicol 1% eye ointment, 4 g
2360F	<i>Chlorsig, QA</i> – CHLORAMPHENICOL , chloramphenicol 0.5% eye drops, 10 mL
5055C	<i>Chlorsig, QA</i> – CHLORAMPHENICOL , chloramphenicol 0.5% eye drops, 10 mL (Dental)
5511C	<i>Chlorsig, QA</i> – CHLORAMPHENICOL , chloramphenicol 1% eye ointment, 4 g (Optometrical)
5512D	<i>Chlorsig, QA</i> – CHLORAMPHENICOL , chloramphenicol 0.5% eye drops, 10 mL (Optometrical)
10099M	<i>GoodLife, JN</i> – GLUCOSE INDICATOR BLOOD , glucose indicator blood strip: diagnostic, 100
10101P	<i>GoodLife, JN</i> – GLUCOSE INDICATOR BLOOD , glucose indicator blood strip: diagnostic, 100
8814X	<i>Panadol Osteo, GC</i> – PARACETAMOL , paracetamol 665 mg tablet: modified release, 96 tablets

Palliative Care

Deletions

Deletion – Brand

5301B	<i>Bisalax, AS</i> – BISACODYL , bisacodyl 5 mg tablet: enteric, 200 tablets
5305F	<i>Bisalax, AS</i> – BISACODYL , bisacodyl 5 mg tablet: enteric, 200 tablets

Alterations

Changes to Restrictions

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

5385K	BENZYDAMINE , benzydamine hydrochloride 0.15% mouthwash, 500 mL (<i>Difflam</i>)
5386L	BENZYDAMINE , benzydamine hydrochloride 0.15% mouthwash, 500 mL (<i>Difflam</i>)
5301B	BISACODYL , bisacodyl 5 mg tablet: enteric, 200 tablets (<i>Lax-Tab</i>)
5302C	BISACODYL , bisacodyl 10 mg/5 mL enema, 25 x 5 mL (<i>Bisalax</i>)
5303D	BISACODYL , bisacodyl 10 mg suppository, 10 (<i>Dulcolax, Petrus Bisacodyl Suppositories</i>)
5304E	BISACODYL , bisacodyl 10 mg suppository, 12 (<i>Petrus Bisacodyl Suppositories</i>)
5305F	BISACODYL , bisacodyl 5 mg tablet: enteric, 200 tablets (<i>Lax-Tab</i>)
5306G	BISACODYL , bisacodyl 10 mg/5 mL enema, 25 x 5 mL (<i>Bisalax</i>)
5307H	BISACODYL , bisacodyl 10 mg suppository, 10 (<i>Dulcolax, Petrus Bisacodyl Suppositories</i>)
5308J	BISACODYL , bisacodyl 10 mg suppository, 12 (<i>Petrus Bisacodyl Suppositories</i>)
5311M	GLYCEROL , glycerol 700 mg suppository, 12 (<i>Petrus Pharmaceuticals Pty Ltd</i>)
5312N	GLYCEROL , glycerol 1.4 g suppository, 12 (<i>Petrus Pharmaceuticals Pty Ltd</i>)
5313P	GLYCEROL , glycerol 2.8 g suppository, 12 (<i>Petrus Pharmaceuticals Pty Ltd</i>)
5314Q	GLYCEROL , glycerol 700 mg suppository, 12 (<i>Petrus Pharmaceuticals Pty Ltd</i>)
5315R	GLYCEROL , glycerol 1.4 g suppository, 12 (<i>Petrus Pharmaceuticals Pty Ltd</i>)
5316T	GLYCEROL , glycerol 2.8 g suppository, 12 (<i>Petrus Pharmaceuticals Pty Ltd</i>)
5317W	HYOSCINE BUTYLBROMIDE , hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules (<i>Buscopan</i>)
5318X	HYOSCINE BUTYLBROMIDE , hyoscine butylbromide 20 mg/mL injection, 5 x 1 mL ampoules (<i>Buscopan</i>)
5423K	METHYLNALTREXONE , methylnaltrexone bromide 12 mg/0.6 mL injection, 1 x 0.6 mL vial (<i>Relistor</i>)
5424L	METHYLNALTREXONE , METHYLNALTREXONE Solution for injection containing methylnaltrexone bromide 12 mg in 0.6 mL, 7 (<i>Relistor</i>)
5359C	NITRAZEPAM , nitrazepam 5 mg tablet, 25 (<i>Alodorm, Mogadon</i>)
5360D	NITRAZEPAM , nitrazepam 5 mg tablet, 25 (<i>Alodorm, Mogadon</i>)
5322D	RHAMNUS FRANGULA + STERCULIA , rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g (<i>Normacol Plus</i>)
5324F	RHAMNUS FRANGULA + STERCULIA , rhamnus frangula 80 mg/g + sterculia 620 mg/g granules, 500 g (<i>Normacol Plus</i>)
5331N	SORBITOL + CITRATE + LAURYL SULFOACETATE SODIUM , sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL (<i>Micolette, Microlax</i>)
5332P	SORBITOL + CITRATE + LAURYL SULFOACETATE SODIUM , sorbitol 3.125 g/5 mL + citrate sodium dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL enema, 12 x 5 mL (<i>Micolette, Microlax</i>)
5375X	TEMAZEPAM , temazepam 10 mg tablet, 25 (<i>APO-Temazepam, Normison, Temaze, Temtabs</i>)
5376Y	TEMAZEPAM , temazepam 10 mg tablet, 25 (<i>APO-Temazepam, Normison, Temaze, Temtabs</i>)

Advance Notices

1 January 2016

Deletion – Brand

5343F	<i>Panadol Osteo, GC</i> – PARACETAMOL , paracetamol 665 mg tablet: modified release, 96 tablets
5344G	<i>Panadol Osteo, GC</i> – PARACETAMOL , paracetamol 665 mg tablet: modified release, 96 tablets

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item

10566D	OCTREOTIDE , octreotide 10 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (<i>Sandostatin LAR</i>)
10549F	OCTREOTIDE , octreotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (<i>Sandostatin LAR</i>)
10558Q	OCTREOTIDE , octreotide 30 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (<i>Sandostatin LAR</i>)
10542W	ZOLEDRONIC ACID , zoledronic acid 4 mg/100 mL injection, 100 mL bag (<i>DBL Zoledronic Acid</i>)
10554L	ZOLEDRONIC ACID , zoledronic acid 4 mg/100 mL injection, 1 x 100 mL vial (<i>Zometa</i>)

Addition – Brand

10057H	<i>Inflectra, HH</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
10184B	<i>Inflectra, HH</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
6397Q	<i>Inflectra, HH</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
6448J	<i>Inflectra, HH</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
6496X	<i>Inflectra, HH</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
9612X	<i>Inflectra, HH</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
9613Y	<i>Inflectra, HH</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
9617E	<i>Inflectra, HH</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
9674E	<i>Inflectra, HH</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
6371H	<i>APO-Zoledronic Acid, TX</i> – ZOLEDRONIC ACID , zoledronic acid 4 mg/5 mL injection, 1 x 5 mL vial
6371H	<i>DBL Zoledronic Acid, HH</i> – ZOLEDRONIC ACID , zoledronic acid 4 mg/5 mL injection, 1 x 5 mL vial

Addition – Equivalence Indicator

10057H	<i>Remicade, JC</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
10184B	<i>Remicade, JC</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
6397Q	<i>Remicade, JC</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
6448J	<i>Remicade, JC</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
6496X	<i>Remicade, JC</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
9612X	<i>Remicade, JC</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
9613Y	<i>Remicade, JC</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
9617E	<i>Remicade, JC</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
9674E	<i>Remicade, JC</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
6426F	<i>Sandostatin LAR, NV</i> – OCTREOTIDE , octreotide 10 mg injection: modified release [1 x 10 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack
6427G	<i>Sandostatin LAR, NV</i> – OCTREOTIDE , octreotide 20 mg injection: modified release [1 x 20 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack
6428H	<i>Sandostatin LAR, NV</i> – OCTREOTIDE , octreotide 30 mg injection: modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack
6371H	<i>Zometa, NV</i> – ZOLEDRONIC ACID , zoledronic acid 4 mg/5 mL injection, 1 x 5 mL vial

Alterations

Changes to Restrictions

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

6120D	DORNASE ALFA , dornase alfa 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules (<i>Pulmozyme</i>)
6459Y	EVEROLIMUS , everolimus 250 microgram tablet, 60 (<i>Certican</i>)
6460B	EVEROLIMUS , everolimus 500 microgram tablet, 60 (<i>Certican</i>)
6461C	EVEROLIMUS , everolimus 750 microgram tablet, 60 (<i>Certican</i>)
9582H	EVEROLIMUS , everolimus 1 mg tablet, 60 (<i>Certican</i>)
2008Q	MANNITOL , MANNITOL Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers, 1 (<i>bronchitol</i>)
1837Q	MYCOPHENOLATE , mycophenolate Capsule 250 mg, 50 (<i>Ceptolate</i>)
6208R	MYCOPHENOLATE , mycophenolate mofetil 250 mg capsule, 100 (<i>APO-Mycophenolate</i> , <i>CellCept</i> , <i>Mycophenolate Sandoz</i> , <i>Pharmacor Mycophenolate 250</i>)
6209T	MYCOPHENOLATE , mycophenolate mofetil 500 mg tablet, 50 (<i>APO-Mycophenolate</i> , <i>CellCept</i> , <i>Ceptolate</i> , <i>Mycophenolate AN</i> , <i>Mycophenolate Sandoz</i> , <i>Pharmacor Mycophenolate 500</i>)
6364Y	MYCOPHENOLATE , mycophenolate mofetil 1 g/5 mL oral liquid: powder for, 165 mL (<i>CellCept</i>)
6426F	OCTREOTIDE , octreotide 10 mg injection: modified release [1 x 10 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack (<i>Sandostatin LAR</i>)
6427G	OCTREOTIDE , octreotide 20 mg injection: modified release [1 x 20 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack (<i>Sandostatin LAR</i>)
6428H	OCTREOTIDE , octreotide 30 mg injection: modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack (<i>Sandostatin LAR</i>)
6436R	SIROLIMUS , sirolimus 1 mg tablet, 100 (<i>Rapamune</i>)
6437T	SIROLIMUS , sirolimus 1 mg/mL oral liquid, 60 mL (<i>Rapamune</i>)
6457W	SIROLIMUS , sirolimus 2 mg tablet, 100 (<i>Rapamune</i>)
9748C	SIROLIMUS , sirolimus 500 microgram tablet, 100 (<i>Rapamune</i>)
6371H	ZOLEDRONIC ACID , zoledronic acid 4 mg/5 mL injection, 1 x 5 mL vial (<i>APO-Zoledronic Acid</i> , <i>DBL Zoledronic Acid</i> , <i>Zometa</i>)

Advance Notices

1 January 2016

Deletion – Brand

6151R	<i>Klacid</i> , GO – CLARITHROMYCIN , clarithromycin 250 mg tablet, 100
6152T	<i>Klacid</i> , GO – CLARITHROMYCIN , clarithromycin 500 mg tablet, 100

1 February 2016

Deletion – Brand

6426F	<i>Sandostatin LAR</i> , NV – OCTREOTIDE , octreotide 10 mg injection: modified release [1 x 10 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack
6427G	<i>Sandostatin LAR</i> , NV – OCTREOTIDE , octreotide 20 mg injection: modified release [1 x 20 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack
6428H	<i>Sandostatin LAR</i> , NV – OCTREOTIDE , octreotide 30 mg injection: modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Item

10543X	OCTREOTIDE , octreotide 10 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (<i>Sandostatin LAR</i>)
10533J	OCTREOTIDE , octreotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (<i>Sandostatin LAR</i>)
10550G	OCTREOTIDE , octreotide 30 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack (<i>Sandostatin LAR</i>)
10548E	ZOLEDRONIC ACID , zoledronic acid 4 mg/100 mL injection, 1 x 100 mL vial (<i>Zometa</i>)
10561W	ZOLEDRONIC ACID , zoledronic acid 4 mg/100 mL injection, 100 mL bag (<i>DBL Zoledronic Acid</i>)

Addition – Brand

10067W	<i>Inflectra, HH</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
10196P	<i>Inflectra, HH</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
5753T	<i>Inflectra, HH</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
5754W	<i>Inflectra, HH</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
5755X	<i>Inflectra, HH</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
5756Y	<i>Inflectra, HH</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
5757B	<i>Inflectra, HH</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
5758C	<i>Inflectra, HH</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
9654D	<i>Inflectra, HH</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
9653C	<i>APO-Zoledronic Acid, TX</i> – ZOLEDRONIC ACID , zoledronic acid 4 mg/5 mL injection, 1 x 5 mL vial
9653C	<i>DBL Zoledronic Acid, HH</i> – ZOLEDRONIC ACID , zoledronic acid 4 mg/5 mL injection, 1 x 5 mL vial

Addition – Equivalence Indicator

10067W	<i>Remicade, JC</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
10196P	<i>Remicade, JC</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
5753T	<i>Remicade, JC</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
5754W	<i>Remicade, JC</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
5755X	<i>Remicade, JC</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
5756Y	<i>Remicade, JC</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
5757B	<i>Remicade, JC</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
5758C	<i>Remicade, JC</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
9654D	<i>Remicade, JC</i> – INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial
9511N	<i>Sandostatin LAR, NV</i> – OCTREOTIDE , octreotide 10 mg injection: modified release [1 x 10 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack
9512P	<i>Sandostatin LAR, NV</i> – OCTREOTIDE , octreotide 20 mg injection: modified release [1 x 20 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack
9513Q	<i>Sandostatin LAR, NV</i> – OCTREOTIDE , octreotide 30 mg injection: modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack
9653C	<i>Zometa, NV</i> – ZOLEDRONIC ACID , zoledronic acid 4 mg/5 mL injection, 1 x 5 mL vial

Alterations

Changes to Restrictions

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

5704F	DORNASE ALFA , dornase alfa 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules (<i>Pulmozyme</i>)
5737Y	EVEROLIMUS , everolimus 1 mg tablet, 60 (<i>Certican</i>)
5738B	EVEROLIMUS , everolimus 250 microgram tablet, 60 (<i>Certican</i>)
5739C	EVEROLIMUS , everolimus 500 microgram tablet, 60 (<i>Certican</i>)
5740D	EVEROLIMUS , everolimus 750 microgram tablet, 60 (<i>Certican</i>)
2015C	MANNITOL , MANNITOL Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers, 1 (<i>bronchitol</i>)
1839T	MYCOPHENOLATE , mycophenolate Capsule 250 mg, 50 (<i>Ceptolate</i>)
9500B	MYCOPHENOLATE , mycophenolate mofetil 1 g/5 mL oral liquid: powder for, 165 mL (<i>CellCept</i>)
9501C	MYCOPHENOLATE , mycophenolate mofetil 250 mg capsule, 100 (<i>APO-Mycophenolate</i> , <i>CellCept</i> , <i>Mycophenolate Sandoz</i> , <i>Pharmacor Mycophenolate 250</i>)
9502D	MYCOPHENOLATE , mycophenolate mofetil 500 mg tablet, 50 (<i>APO-Mycophenolate</i> , <i>CellCept</i> , <i>Ceptolate</i> , <i>Mycophenolate AN</i> , <i>Mycophenolate Sandoz</i> , <i>Pharmacor Mycophenolate 500</i>)
9511N	OCTREOTIDE , octreotide 10 mg injection: modified release [1 x 10 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack (<i>Sandostatin LAR</i>)
9512P	OCTREOTIDE , octreotide 20 mg injection: modified release [1 x 20 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack (<i>Sandostatin LAR</i>)
9513Q	OCTREOTIDE , octreotide 30 mg injection: modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack (<i>Sandostatin LAR</i>)
9548M	SIROLIMUS , sirolimus 2 mg tablet, 100 (<i>Rapamune</i>)
9549N	SIROLIMUS , sirolimus 1 mg tablet, 100 (<i>Rapamune</i>)
9550P	SIROLIMUS , sirolimus 1 mg/mL oral liquid, 60 mL (<i>Rapamune</i>)
9747B	SIROLIMUS , sirolimus 500 microgram tablet, 100 (<i>Rapamune</i>)
9653C	ZOLEDRONIC ACID , zoledronic acid 4 mg/5 mL injection, 1 x 5 mL vial (<i>APO-Zoledronic Acid</i> , <i>DBL Zoledronic Acid</i> , <i>Zometa</i>)

Advance Notices

1 January 2016

Deletion – Brand

5624B	<i>Klacid</i> , GO – CLARITHROMYCIN , clarithromycin 500 mg tablet, 100
5625C	<i>Klacid</i> , GO – CLARITHROMYCIN , clarithromycin 250 mg tablet, 100

1 February 2016

Deletion – Brand

9511N	<i>Sandostatin LAR</i> , NV – OCTREOTIDE , octreotide 10 mg injection: modified release [1 x 10 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack
9512P	<i>Sandostatin LAR</i> , NV – OCTREOTIDE , octreotide 20 mg injection: modified release [1 x 20 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack
9513Q	<i>Sandostatin LAR</i> , NV – OCTREOTIDE , octreotide 30 mg injection: modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack

Highly Specialised Drugs Program (Community Access)

Alterations

Changes to Restrictions

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

10344K **TIPRANAVIR**, tipranavir 250 mg capsule, 120 (*Aptivus*)

Growth Hormone Program

Additions

Addition – Item

10507B **SOMATROPIN**, somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (*Omnitrope Surepal 5*)

10512G **SOMATROPIN**, somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (*Omnitrope Surepal 5*)

10518N **SOMATROPIN**, somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (*Omnitrope Surepal 5*)

10506Y **SOMATROPIN**, somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (*Omnitrope Surepal 10*)

10514J **SOMATROPIN**, somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (*Omnitrope Surepal 10*)

10519P **SOMATROPIN**, somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (*Omnitrope Surepal 10*)

Repatriation Pharmaceutical Benefits

Additions

Addition – Brand

4696E *Tielle MTL103, KI* – **DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM**, dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm dressing: island, 5 dressings

Deletions

Deletion – Brand

4696E *Tielle MT2442, KI* – **DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM**, dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm dressing: island, 5 dressings

Alterations

Changes to Restrictions

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

4077N **ASPIRIN**, aspirin 100 mg tablet: enteric, 84 (*Cartia, Pharmacy Action Low Dose Aspirin*)

4078P **ASPIRIN**, aspirin 100 mg capsule: enteric, 84 (*Astrix*)

4115N	AZITHROMYCIN , azithromycin 500 mg tablet, 3 (<i>APO-Azithromycin, Azithromycin Sandoz, Azithromycin-GA, Chem mart Azithromycin, Terry White Chemists Azithromycin, Zedd 500, Zithromax, Zitrocin</i>)
4050E	BANDAGE COMPRESSION , bandage compression bandage: two layer, 1 bandage (<i>Coban 2</i>)
4598B	BANDAGE COMPRESSION , bandage compression bandage: four layer, 1 bandage (<i>Profore Lite 66050415</i>)
4658E	BANDAGE COMPRESSION , bandage compression bandage: four layer, 1 bandage (<i>Profore 66050016</i>)
4670T	BANDAGE ZINC PASTE , bandage zinc paste 10 cm x 9.1 m bandage, 1 (<i>Flexidress 650941</i>)
4750B	BANDAGE ZINC PASTE , bandage zinc paste 7.5 cm x 6 m bandage, 1 (<i>Viscopaste 4948</i>)
4760M	BANDAGE ZINC PASTE , bandage zinc paste 80 cm (stockings) bandage, 4 (<i>ZipZoc 66000747</i>)
4150K	BROMAZEPAM , bromazepam 3 mg tablet, 30 (<i>Lexotan</i>)
4151L	BROMAZEPAM , bromazepam 6 mg tablet, 30 (<i>Lexotan</i>)
4144D	BUSPIRONE , buspirone hydrochloride 5 mg tablet, 50 (<i>Buspar</i>)
4145E	BUSPIRONE , buspirone hydrochloride 10 mg tablet, 50 (<i>Buspar</i>)
4931M	CADEXOMER-IODINE , cadexomer-iodine 3 g powder: dusting sterile, 7 x 3 g sachets (<i>Iodosorb Powder 66051070</i>)
4932N	CADEXOMER-IODINE , cadexomer-iodine 50% (500 mg/g) ointment, 4 x 10 g tubes (<i>Iodosorb Ointment 66051240</i>)
4933P	CADEXOMER-IODINE , cadexomer-iodine 50% (500 mg/g) ointment, 2 x 20 g tubes (<i>Iodosorb Ointment 66051230</i>)
4935R	CADEXOMER-IODINE , DRESSING with CADEXOMER IODINE Sheets 5 g (6 cm x 4 cm), 5, 1 (<i>Iodosorb 66051330</i>)
4936T	CADEXOMER-IODINE , cadexomer-iodine 8 cm x 6 cm dressing, 3 x 10 g sheets (<i>Iodosorb 66051340</i>)
4937W	CADEXOMER-IODINE , DRESSING with CADEXOMER IODINE Sheets 17 g (10 cm x 8 cm), 2, 1 (<i>Iodosorb 66051360</i>)
4055K	CALCIUM CARBONATE + GLYCINE , calcium carbonate 420 mg + glycine 180 mg tablet: chewable, 100 (<i>Titralac</i>)
1905G	DRESSING ALGINATE CAVITY WOUND , DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 5 (<i>Kaltostat 168117</i>)
4682K	DRESSING ALGINATE CAVITY WOUND , dressing alginate cavity wound 2 g (40 cm) rope, 6 x 2 g (<i>Comfeel SeaSorb Filler 3740</i>)
4832H	DRESSING ALGINATE CAVITY WOUND , DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 1 (<i>Sorbsan 1411</i>)
4683L	DRESSING ALGINATE SUPERFICIAL WOUND , dressing alginate superficial wound 7.5 cm x 12 cm dressing, 10 (<i>Kaltostat 168212</i>)
4684M	DRESSING ALGINATE SUPERFICIAL WOUND , dressing alginate superficial wound 5 cm x 5 cm dressing, 1 (<i>Comfeel SeaSorb Dressing 3705</i>)
4691X	DRESSING ALGINATE SUPERFICIAL WOUND , dressing alginate superficial wound 15 cm x 20 cm dressing, 10 (<i>Algisite M 66000521</i>)
4699H	DRESSING ALGINATE SUPERFICIAL WOUND , dressing alginate superficial wound 5 cm x 5 cm dressing, 10 (<i>Algisite M 66000519, Kaltostat 168210</i>)
4700J	DRESSING ALGINATE SUPERFICIAL WOUND , dressing alginate superficial wound 10 cm x 10 cm dressing, 10 (<i>Algisite M 66000520</i>)
4831G	DRESSING ALGINATE SUPERFICIAL WOUND , dressing alginate superficial wound 10 cm x 10 cm dressing, 1 (<i>Comfeel SeaSorb Dressing 3710, Sorbsan 1410</i>)
4893M	DRESSING FILM , dressing film 10 cm x 12 cm dressing, 10 (<i>Op-Site Flexigrid 4629</i>)
4898T	DRESSING FILM ISLAND , dressing film island 5 cm x 7.2 cm dressing, 5 (<i>Cutifilm Plus 36361370</i>)
4899W	DRESSING FILM ISLAND , dressing film island 8 cm x 10 cm dressing, 5 (<i>Cutifilm Plus 36361371</i>)
4795J	DRESSING FOAM HEAVY EXUDATE , dressing foam heavy exudate 10 cm x 10 cm dressing, 10 (<i>Allevyn 66007637</i>)
4590N	DRESSING FOAM MODERATE EXUDATE , dressing foam moderate exudate 12.5 cm x 12.5 cm dressing, 10 (<i>Allevyn Adhesive 66000044</i>)
4694C	DRESSING FOAM MODERATE EXUDATE , dressing foam moderate exudate cavity conforming foam, 1 x 20 g sachet (<i>Cavicare 4563</i>)
2439J	DRESSING FOAM WITH SILICONE AND SILVER , dressing foam with silicone and silver 10 cm x 10 cm dressing, 5 (<i>Mepilex Ag</i>)

2470B	DRESSING FOAM WITH SILICONE AND SILVER , dressing foam with silicone and silver 10 cm x 10 cm dressing, 5 (<i>Mepilex Border Ag</i>)
4196W	DRESSING FOAM WITH SILICONE HEAVY EXUDATE , dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 10 (<i>Allevyn Gentle 66800248</i>)
4207K	DRESSING FOAM WITH SILICONE HEAVY EXUDATE , dressing foam with silicone heavy exudate 7.5 cm x 7.5 cm dressing, 10 (<i>Allevyn Gentle Border 66800269</i>)
4230P	DRESSING FOAM WITH SILICONE HEAVY EXUDATE , dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 10 (<i>Allevyn Gentle Border 66800270</i>)
4642H	DRESSING FOAM WITH SILICONE HEAVY EXUDATE , dressing foam with silicone heavy exudate 7.5 cm x 7.5 cm dressing, 5 (<i>Mepilex Border 295200</i>)
4643J	DRESSING FOAM WITH SILICONE HEAVY EXUDATE , dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 5 (<i>Mepilex Border 295300</i>)
4644K	DRESSING FOAM WITH SILICONE LIGHT EXUDATE , dressing foam with silicone light exudate 6 cm x 8.5 cm dressing, 5 (<i>Mepilex Lite 284000</i>)
4645L	DRESSING FOAM WITH SILICONE LIGHT EXUDATE , dressing foam with silicone light exudate 10 cm x 10 cm dressing, 5 (<i>Mepilex Lite 284100</i>)
4626L	DRESSING FOAM WITH SILICONE MODERATE EXUDATE , dressing foam with silicone moderate exudate 10 cm x 10 cm dressing, 5 (<i>Mepilex 294100</i>)
4252T	DRESSING FOAM WITH SILVER , dressing foam with silver 7.5 cm x 7.5 cm dressing, 10 (<i>Allevyn Ag Adhesive 66800073</i>)
4255Y	DRESSING FOAM WITH SILVER , dressing foam with silver 10 cm x 10 cm dressing, 10 (<i>Allevyn Ag Adhesive 66800075</i>)
4258D	DRESSING FOAM WITH SILVER , dressing foam with silver 12.5 cm x 12.5 cm dressing, 10 (<i>Allevyn Ag Adhesive 66800078</i>)
4259E	DRESSING FOAM WITH SILVER , dressing foam with silver 10 cm x 10 cm dressing, 10 (<i>Allevyn Ag Non-Adhesive 66800086</i>)
4263J	DRESSING FOAM WITH SILVER , dressing foam with silver 7.5 cm x 7.5 cm dressing, 10 (<i>Allevyn Ag Gentle Border 66800460</i>)
4266M	DRESSING FOAM WITH SILVER , dressing foam with silver 10 cm x 10 cm dressing, 10 (<i>Allevyn Ag Gentle Border 66800461</i>)
4270R	DRESSING FOAM WITH SILVER , dressing foam with silver 12.5 cm x 12.5 cm dressing, 10 (<i>Allevyn Ag Gentle Border 66800462</i>)
4759L	DRESSING GAUZE PARAFFIN , dressing gauze paraffin 10 cm x 10 cm dressing, 10 (<i>Jelonet 7404</i>)
4845B	DRESSING GAUZE PARAFFIN WITH CHLORHEXIDINE ACETATE , dressing gauze paraffin with chlorhexidine acetate 10 cm x 10 cm dressing, 10 (<i>Bactigras 7457</i>)
4918W	DRESSING HYDROACTIVE CAVITY WOUND , dressing hydroactive cavity wound 5 cm x 6 cm dressing, 10 (<i>Allevyn Plus Cavity 66047571</i>)
4919X	DRESSING HYDROACTIVE CAVITY WOUND , dressing hydroactive cavity wound 10 cm x 10 cm dressing, 5 (<i>Allevyn Plus Cavity 66047573</i>)
4948K	DRESSING HYDROACTIVE DEBRIDEMENT , DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 5.5 cm, 10, 1 (<i>TenderWet Active Cavity 609272</i>)
4949L	DRESSING HYDROACTIVE DEBRIDEMENT , DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 4 cm, 10, 1 (<i>TenderWet 24 Active 609210</i>)
4950M	DRESSING HYDROACTIVE DEBRIDEMENT , DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 7.5 cm x 7.5 cm, 10, 1 (<i>TenderWet 24 Active 609213</i>)
4927H	DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM , dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 10 cm x 10 cm pad: waterproof, 10 pads (<i>Biatain Non-adhesive 3410</i>)
4928J	DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM , dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 15 cm pad: waterproof, 5 pads (<i>Biatain Non-adhesive 3413</i>)
4929K	DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM , dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 12 cm x 12 cm pad: waterproof, 10 pads (<i>Biatain Adhesive 3420</i>)

4930L	DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM , dressing hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm pad: waterproof, 5 pads (<i>Biatain Adhesive 3423</i>)
4905E	DRESSING HYDROACTIVE SUPERFICIAL WOUND LIGHT EXUDATE , dressing hydroactive superficial wound light exudate 5 cm x 6 cm dressing, 10 (<i>Allevyn Thin 66047576</i>)
4906F	DRESSING HYDROACTIVE SUPERFICIAL WOUND LIGHT EXUDATE , dressing hydroactive superficial wound light exudate 10 cm x 10 cm dressing, 5 (<i>Allevyn Thin 66047578</i>)
4885D	DRESSING HYDROACTIVE SUPERFICIAL WOUND MODERATE EXUDATE , dressing hydroactive superficial wound moderate exudate 5 cm x 6 cm dressing, 10 (<i>Cutinova Hydro 66047441</i>)
4886E	DRESSING HYDROACTIVE SUPERFICIAL WOUND MODERATE EXUDATE , dressing hydroactive superficial wound moderate exudate 10 cm x 10 cm dressing, 5 (<i>Cutinova Hydro 66047443</i>)
10097K	DRESSING HYDROFIBRE WITH SILVER , dressing hydrofibre with silver 10 cm x 10 cm dressing, 10 (<i>Aquacel Ag 403708</i>)
10098L	DRESSING HYDROFIBRE WITH SILVER , dressing hydrofibre with silver 15 cm x 15 cm dressing, 5 (<i>Aquacel Ag 403710</i>)
10105W	DRESSING HYDROFIBRE WITH SILVER , dressing hydrofibre with silver 2 cm x 45 cm rope, 5 (<i>Aquacel Ag 403771</i>)
4646M	DRESSING WITH SILVER , dressing with silver 10 cm x 10 cm dressing: hydroactive, 5 dressings (<i>Biatain Ag 9622</i>)
4647N	DRESSING WITH SILVER , dressing with silver 12.5 cm x 12.5 cm dressing: hydroactive, 5 dressings (<i>Biatain Ag 9632</i>)
4648P	DRESSING WITH SILVER , dressing with silver 10 cm x 10 cm dressing: tulle, 3 dressings (<i>Atrauman Ag 499572</i>)
4216X	FLUNITRAZEPAM , flunitrazepam 1 mg tablet, 30 (<i>Hypnodorm</i>)
4246L	GLYCEROL , glycerol 2.8 g suppository, 12 (<i>Petrus Pharmaceuticals Pty Ltd</i>)
4281H	ICHTHAMMOL , ichthammol Cream 5 mg-10 mg-10 mg per g (0.5%-1%-1%), 50 g, 1 (<i>Egoderma Cream</i>)
4280G	ICHTHAMMOL + ZINC OXIDE , ichthammol 1% (10 mg/g) + zinc oxide 15% (150 mg/g) ointment, 50 g (<i>Egoderma Ointment</i>)
4342M	MOMETASONE , mometasone furoate 0.1% (1 mg/g) cream, 50 g (<i>Elocon</i>)
4343N	MOMETASONE , mometasone furoate 0.1% (1 mg/g) ointment, 50 g (<i>Elocon</i>)
4510J	PANTHENOL , panthenol conditioner, 200 g (<i>SebiRinse</i>)
4408B	PINE TAR WITH TRIETHANOLAMINE LAURYL SULFATE , PINE TAR with TRIETHANOLAMINE LAURYL SULFATE Solution 23 mg-60 mg per mL (2.3%-6%), 500 mL, 1 (<i>Pinetarsol</i>)

Prescriber Bag

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

10016E	Max.Qty Packs	DPMQ \$	Brand Name and Manufacturer
	1	276.21	Benztropine Omega [FK]

General Pharmaceutical Benefits

■ ACITRETIN

Caution This drug is a potent teratogen - pregnancy should be avoided for at least two years after cessation of therapy.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Authority required (STREAMLINED)

5789

Severe intractable psoriasis

Authority required (STREAMLINED)

5727

Severe disorders of keratinisation

acitretin 10 mg capsule, 100

2019G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	144.09	37.70	^a Acitretin Actavis [GN] ^a Novatin [TX]	^a Neotigason [UA]

acitretin 25 mg capsule, 100

2020H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	285.47	37.70	^a Acitretin Actavis [GN] ^a Novatin [TX]	^a Neotigason [UA]

■ ACLIDINIUM + EFORMOTEROL

Note The treatment must not be used in combination with an ICS/LABA, or LAMA or LABA monotherapy.

Note A LABA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, eformoterol or vilanterol.

Note This product is not PBS-subsidised for the treatment of asthma.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Authority required (STREAMLINED)

5763

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

Patient must have been stabilised on a combination of a long acting muscarinic antagonist and long acting beta-2 agonist.

aclidinium 340 microgram/actuation + eformoterol fumarate dihydrate 12 microgram/actuation inhalation: powder for, 60 actuations

10565C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	91.89	37.70	Brimica Genuair [FK]

■ ALBENDAZOLE

Authority required (STREAMLINED)

5607

Hydatid disease

Clinical criteria:

The treatment must be in conjunction with surgery; OR

The treatment must be used when a surgical cure cannot be achieved; OR

The treatment must be used when surgery cannot be used.

albendazole 400 mg tablet: chewable, 60

8459F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	172.99	37.70	Eskazole [AS]

■ ALBENDAZOLE

Authority required (STREAMLINED)

5680

Tapeworm infestation

albendazole 200 mg tablet: chewable, 6

8503M

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	1	..	33.62	34.79	Zentel [AS]

■ ALBENDAZOLE**Authority required (STREAMLINED)****5817**

Whipworm infestation

Population criteria:

Patient must be an Aboriginal or a Torres Strait Islander person.

Authority required (STREAMLINED)**5712**

Strongyloidiasis

Authority required (STREAMLINED)**5797**

Hookworm infestation

albendazole 200 mg tablet: chewable, 6

9047E

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	..	..	33.62	34.79	Zentel [AS]

■ ALPRAZOLAM**Authority required**

Panic disorder

Clinical criteria:

The treatment must be for use when other treatments have failed; OR

The treatment must be for use when other treatments are inappropriate.

alprazolam 1 mg tablet, 50

2132F

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	17.92	19.09	^a Alprax 1 [QA] ^a GenRx Alprazolam [GX] ^a Terry White Chemists Alprazolam [TW]	^a Chem mart Alprazolam [CH] ^a Kalma 1 [AF]

alprazolam 2 mg tablet, 50

8118G

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	2	..	20.45	21.62	^a Alprax 2 [QA] ^a GenRx Alprazolam [GX] ^a Terry White Chemists Alprazolam [TW]	^a Chem mart Alprazolam [CH] ^a Kalma 2 [AF]

alprazolam 250 microgram tablet, 50

2130D

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	14.96	16.13	^a Alprax 0.25 [QA]	^a Kalma 0.25 [AF]

alprazolam 500 microgram tablet, 50

2131E

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	15.97	17.14	^a Alprax 0.5 [QA]	^a Kalma 0.5 [AF]

■ AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE**Restricted benefit**

Phenylketonuria

amino acid formula with vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine oral liquid: powder for, 400 g

8479G

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
8	5	..	*697.97	37.70	PKU Anamix infant [SB]

■ AMINO ACID FORMULA WITHOUT PHENYLALANINE**Restricted benefit**

Phenylketonuria

amino acid formula without phenylalanine 1 g tablet, 75

8678R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	24	5	..	*1417.65	37.70	Phlexy-10 [SB]

amino acid formula without phenylalanine 500 mg capsule, 200

8554F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	16	5	..	*1268.05	37.70	Phlexy-10 [SB]

amino acid formula without phenylalanine oral liquid: powder for, 30 x 20 g sachets

2347M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	7	5	..	*1453.62	37.70	Phlexy-10 Drink Mix [SB]

■ AMIODARONE

Note This drug has been reported to cause frequent and potentially serious toxicity.

Note Regular monitoring of hepatic and thyroid function is recommended.

Note Shared Care Model:

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

Restricted benefit

Severe cardiac arrhythmias

amiodarone hydrochloride 100 mg tablet, 30

2344J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.77	15.94	^a Aratac 100 [AF]	^a Cordarone X 100 [SW]

amiodarone hydrochloride 200 mg tablet, 30

2343H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.16	19.33	^a Amiodarone Sandoz [SZ] ^a Chem mart Amiodarone [CH] ^a GenRx Amiodarone [GX] ^a Terry White Chemists Amiodarone [TW]	^a Aratac 200 [AF] ^a Cordarone X 200 [SW] ^a Rithmik 200 [QA]

■ AMISULPRIDE

Note Shared Care Model:

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

Authority required (STREAMLINED)

4246

Schizophrenia

amisulpride 100 mg tablet, 30

8594H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	21.25	22.42	^a Amisulpride 100 Winthrop [WA] ^a APO-Amisulpride [TX] ^a Sulprix [AF]	^a Amisulpride Sandoz [SZ] ^a Solian 100 [SW]

amisulpride 100 mg/mL oral liquid, 60 mL

8736T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*139.81	37.70	Solian Solution [SW]

amisulpride 200 mg tablet, 60

8595J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	57.03	37.70	^a Amisulpride 200 Winthrop [WA] ^a APO-Amisulpride [TX] ^a Sulprix [AF]	^a Amisulpride Sandoz [SZ] ^a Solian 200 [SW]

amisulpride 400 mg tablet, 60

8596K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	94.94	37.70	^a Amipride 400 [QA] ^a Amisulpride Sandoz [SZ] ^a Solian 400 [SW]	^a Amisulpride 400 Winthrop [WA] ^a APO-Amisulpride [TX] ^a Sulprix [AF]

■ AMLODIPINE + ATORVASTATIN

Restricted benefit

Hypertension

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
Patient must be currently receiving treatment with a dihydropyridine calcium channel blocker.

Restricted benefit

Angina

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
Patient must be currently receiving treatment with a dihydropyridine calcium channel blocker.

Restricted benefit

Hypertension

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
Patient must be one in whom blood pressure is inadequately controlled with other classes of antihypertensive agents, **AND**
The treatment must be appropriate for use as adjunctive therapy with a dihydropyridine calcium channel blocker.

Restricted benefit

Angina

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
Patient must have angina which is inadequately controlled with other classes of anti-anginal agents, **AND**
The treatment must be appropriate for use as adjunctive therapy with a dihydropyridine calcium channel blocker.

Restricted benefit

Hypertension

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
Patient must be intolerant of the side effects of other classes of antihypertensive agents, **AND**
Patient must be one in whom replacement therapy with a dihydropyridine calcium channel blocker would be appropriate.

Restricted benefit

Angina

Clinical criteria:

Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
Patient must be intolerant of the side effects of other classes of anti-anginal agents, **AND**
Patient must be one in whom replacement therapy with a dihydropyridine calcium channel blocker would be appropriate.

amlodipine 10 mg + atorvastatin 10 mg tablet, 30

9053L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	37.90	37.70	^a APO-Amlodipine/Atorvastatin 10/10 [TX]	^a Blooms the Chemist Amlodipine/Atorvastatin 10/10 [IB]
						^a Cadatin 10/10 [FZ]	^a Cadivast 10/10 [AF]
						^a Caduet 10/10 [PF]	^a Chem mart Amlodipine/Atorvastatin 10/10 [CH]
						^a Terry White Chemists Amlodipine/Atorvastatin 10/10 [TW]	

amlodipine 10 mg + atorvastatin 20 mg tablet, 30

9054M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	48.03	37.70	^a APO-Amlodipine/Atorvastatin 10/20 [TX]	^a Blooms the Chemist Amlodipine/Atorvastatin 10/20 [IB]
						^a Cadatin 10/20 [FZ]	^a Cadivast 10/20 [AF]
						^a Caduet 10/20 [PF]	^a Chem mart Amlodipine/Atorvastatin 10/20 [CH]
						^a Terry White Chemists Amlodipine/Atorvastatin 10/20 [TW]	

amlodipine 10 mg + atorvastatin 40 mg tablet, 30

9055N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	60.88	37.70	^a APO-Amlodipine/Atorvastatin 10/40 [TX]	^a Blooms the Chemist Amlodipine/Atorvastatin 10/40 [IB]
						^a Cadatin 10/40 [FZ]	^a Cadivast 10/40 [AF]

^a Caduet 10/40 [PF] ^a Chem mart
Amlodipine/Atorvastatin 10/40
[CH]

^a Terry White Chemists
Amlodipine/Atorvastatin 10/40
[TW]

amlodipine 10 mg + atorvastatin 80 mg tablet, 30

9056P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	79.92	37.70	^a APO-Amlodipine/Atorvastatin 10/80 [TX]	^a Blooms the Chemist Amlodipine/Atorvastatin 10/80 [IB]
						^a Cadatin 10/80 [FZ]	^a Cadivast 10/80 [AF]
						^a Caduet 10/80 [PF]	^a Chem mart Amlodipine/Atorvastatin 10/80 [CH]
						^a Terry White Chemists Amlodipine/Atorvastatin 10/80 [TW]	

amlodipine 5 mg + atorvastatin 10 mg tablet, 30

9049G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	35.26	36.43	^a APO-Amlodipine/Atorvastatin 5/10 [TX]	^a Blooms the Chemist Amlodipine/Atorvastatin 5/10 [IB]
						^a Cadatin 5/10 [FZ]	^a Cadivast 5/10 [AF]
						^a Caduet 5/10 [PF]	^a Chem mart Amlodipine/Atorvastatin 5/10 [CH]
						^a Terry White Chemists Amlodipine/Atorvastatin 5/10 [TW]	

amlodipine 5 mg + atorvastatin 20 mg tablet, 30

9050H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	45.40	37.70	^a APO-Amlodipine/Atorvastatin 5/20 [TX]	^a Blooms the Chemist Amlodipine/Atorvastatin 5/20 [IB]
						^a Cadatin 5/20 [FZ]	^a Cadivast 5/20 [AF]
						^a Caduet 5/20 [PF]	^a Chem mart Amlodipine/Atorvastatin 5/20 [CH]
						^a Terry White Chemists Amlodipine/Atorvastatin 5/20 [TW]	

amlodipine 5 mg + atorvastatin 40 mg tablet, 30

9051J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	58.24	37.70	^a APO-Amlodipine/Atorvastatin 5/40 [TX]	^a Blooms the Chemist Amlodipine/Atorvastatin 5/40 [IB]
						^a Cadatin 5/40 [FZ]	^a Cadivast 5/40 [AF]
						^a Caduet 5/40 [PF]	^a Chem mart Amlodipine/Atorvastatin 5/40 [CH]
						^a Terry White Chemists Amlodipine/Atorvastatin 5/40 [TW]	

amlodipine 5 mg + atorvastatin 80 mg tablet, 30

9052K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	77.29	37.70	^a APO-Amlodipine/Atorvastatin 5/80 [TX]	^a Blooms the Chemist Amlodipine/Atorvastatin 5/80 [IB]
						^a Cadatin 5/80 [FZ]	^a Cadivast 5/80 [AF]
						^a Caduet 5/80 [PF]	^a Chem mart Amlodipine/Atorvastatin 5/80 [CH]
						^a Terry White Chemists Amlodipine/Atorvastatin 5/80 [TW]	

▪ ARTEMETHER + LUMEFANTRINE

Note This drug is not PBS-subsidised for prophylaxis of malaria.

Authority required

Confirmed or suspected Plasmodium falciparum malaria

Clinical criteria:

Patient must be unable to swallow a solid dosage form of artemether with lumefantrine.

artemether 20 mg + lumefantrine 120 mg tablet: dispersible, 18

5296R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	92.67	37.70	Riamet 20mg/120mg Dispersible [NV]

■ ARTEMETHER + LUMEFANTRINE**Note** This drug is not PBS-subsidised for prophylaxis of malaria.**Authority required**

Confirmed or suspected Plasmodium falciparum malaria

artemether 20 mg + lumefantrine 120 mg tablet, 24

9498X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	92.67	37.70	Riamet [NV]

■ ASENAPINE**Note Shared Care Model:**

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

Authority required (STREAMLINED)**4246**

Schizophrenia

Authority required (STREAMLINED)**5773**

Acute mania or mixed episodes

Clinical criteria:The condition must be associated with bipolar I disorder, **AND**

The treatment must be limited to up to 6 months per episode.

Authority required (STREAMLINED)**5719**

Bipolar I disorder

Clinical criteria:The treatment must be maintenance therapy, **AND**

The treatment must be as monotherapy.

asenapine 10 mg wafer: sublingual, 60 wafers

5141N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	240.41	37.70	Saphris [LU]

asenapine 5 mg wafer: sublingual, 60 wafers

5140M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	147.37	37.70	Saphris [LU]

■ ATORVASTATIN**Restricted benefit**

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

atorvastatin 10 mg tablet, 30

8213G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	13.41	14.58	^a APO-Atorvastatin [TX] ^a Atorvastatin AN [EA] ^a Atorvastatin Pfizer [FZ] ^a Atorvastatin SCP 10 [RZ] ^a Blooms the Chemist Atorvastatin [IB] ^a Lipitor [PF] ^a Terry White Chemists Atorvastatin [TW] ^a Trovas [RA]	^a Atorvachol [ED] ^a Atorvastatin GH [GQ] ^a Atorvastatin Sandoz [SZ] ^a Atorvastatin SZ [HX] ^a Chem mart Atorvastatin [CH] ^a Lorstat 10 [AF] ^a Torvastat 10 [QA]

atorvastatin 20 mg tablet, 30

8214H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.83	16.00	^a APO-Atorvastatin [TX]	^a Atorvachol [ED]

^a Atorvastatin AN [EA]
^a Atorvastatin Pfizer [FZ]
^a Atorvastatin SCP 20 [RZ]
^a Blooms the Chemist
 Atorvastatin [IB]
^a Lipitor [PF]
^a Terry White Chemists
 Atorvastatin [TW]
^a Trovas [RA]

^a Atorvastatin GH [GQ]
^a Atorvastatin Sandoz [SZ]
^a Atorvastatin SZ [HX]
^a Chem mart Atorvastatin [CH]
^a Lorstat 20 [AF]
^a Torvastat 20 [QA]

atorvastatin 40 mg tablet, 30

8215J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.62	17.79	^a APO-Atorvastatin [TX] ^a Atorvastatin AN [EA] ^a Atorvastatin Pfizer [FZ] ^a Atorvastatin SCP 40 [RZ] ^a Blooms the Chemist Atorvastatin [IB] ^a Lipitor [PF] ^a Terry White Chemists Atorvastatin [TW] ^a Trovas [RA]	^a Atorvachol [ED] ^a Atorvastatin GH [GQ] ^a Atorvastatin Sandoz [SZ] ^a Atorvastatin SZ [HX] ^a Chem mart Atorvastatin [CH] ^a Lorstat 40 [AF] ^a Torvastat 40 [QA]

atorvastatin 80 mg tablet, 30

8521L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.29	20.46	^a APO-Atorvastatin [TX] ^a Atorvastatin AN [EA] ^a Atorvastatin Pfizer [FZ] ^a Atorvastatin SCP 80 [RZ] ^a Blooms the Chemist Atorvastatin [IB] ^a Lipitor [PF] ^a Terry White Chemists Atorvastatin [TW] ^a Trovas [RA]	^a Atorvachol [ED] ^a Atorvastatin GH [GQ] ^a Atorvastatin Sandoz [SZ] ^a Atorvastatin SZ [HX] ^a Chem mart Atorvastatin [CH] ^a Lorstat 80 [AF] ^a Torvastat 80 [QA]

■ ATORVASTATIN

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

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

Restricted benefit

For use in patients who meet the criteria set out in the General Statement for Lipid-Lowering Drugs

Clinical criteria:

Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

atorvastatin 10 mg tablet, 30

9230T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	13.41	14.58	^a APO-Atorvastatin [TX] ^a Atorvastatin AN [EA] ^a Atorvastatin Pfizer [FZ] ^a Atorvastatin SCP 10 [RZ] ^a Blooms the Chemist Atorvastatin [IB] ^a Lipitor [PF] ^a Terry White Chemists Atorvastatin [TW] ^a Trovas [RA]	^a Atorvachol [ED] ^a Atorvastatin GH [GQ] ^a Atorvastatin Sandoz [SZ] ^a Atorvastatin SZ [HX] ^a Chem mart Atorvastatin [CH] ^a Lorstat 10 [AF] ^a Torvastat 10 [QA]

atorvastatin 20 mg tablet, 30

9231W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	14.83	16.00	^a APO-Atorvastatin [TX] ^a Atorvastatin AN [EA] ^a Atorvastatin Pfizer [FZ] ^a Atorvastatin SCP 20 [RZ] ^a Blooms the Chemist Atorvastatin [IB] ^a Lipitor [PF] ^a Terry White Chemists Atorvastatin [TW] ^a Trovas [RA]	^a Atorvachol [ED] ^a Atorvastatin GH [GQ] ^a Atorvastatin Sandoz [SZ] ^a Atorvastatin SZ [HX] ^a Chem mart Atorvastatin [CH] ^a Lorstat 20 [AF] ^a Torvastat 20 [QA]

atorvastatin 40 mg tablet, 30

9232X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	16.62	17.79	^a APO-Atorvastatin [TX] ^a Atorvastatin AN [EA] ^a Atorvastatin Pfizer [FZ] ^a Atorvastatin SCP 40 [RZ] ^a Blooms the Chemist Atorvastatin [IB] ^a Lipitor [PF] ^a Terry White Chemists Atorvastatin [TW] ^a Trovas [RA]	^a Atorvachol [ED] ^a Atorvastatin GH [GQ] ^a Atorvastatin Sandoz [SZ] ^a Atorvastatin SZ [HX] ^a Chem mart Atorvastatin [CH] ^a Lorstat 40 [AF] ^a Torvastat 40 [QA]

atorvastatin 80 mg tablet, 30

9233Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	19.29	20.46	^a APO-Atorvastatin [TX] ^a Atorvastatin AN [EA] ^a Atorvastatin Pfizer [FZ] ^a Atorvastatin SCP 80 [RZ] ^a Blooms the Chemist Atorvastatin [IB] ^a Lipitor [PF] ^a Terry White Chemists Atorvastatin [TW] ^a Trovas [RA]	^a Atorvachol [ED] ^a Atorvastatin GH [GQ] ^a Atorvastatin Sandoz [SZ] ^a Atorvastatin SZ [HX] ^a Chem mart Atorvastatin [CH] ^a Lorstat 80 [AF] ^a Torvastat 80 [QA]

■ ATOVAQUONE**Note Shared Care Model:**

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

Authority required (STREAMLINED)**5609**

Mild to moderate *Pneumocystis carinii* pneumonia

Population criteria:

Patient must be an adult, **AND**

Patient must be intolerant of trimethoprim/sulfamethoxazole therapy.

atovaquone 750 mg/5 mL oral liquid, 210 mL

8300W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	1027.33	37.70	Wellvone [AS]

■ ATOVAQUONE + PROGUANIL

Note This drug is not PBS-subsidised for prophylaxis of malaria.

Note Shared Care Model:

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

Authority required

Confirmed or suspected *Plasmodium falciparum* malaria

Clinical criteria:

The treatment must be used where quinine containing regimens are inappropriate.

Population criteria:

Patient must be aged 3 years or older.

atovaquone 250 mg + proguanil hydrochloride 100 mg tablet, 12

9439T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	65.49	37.70	Malarone [GK]

■ AXITINIB

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

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

Note Special Pricing Arrangements apply.

Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)
Treatment Phase: Continuing treatment beyond 3 months

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**

The treatment must be the sole PBS-subsidised therapy for this condition.

Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

axitinib 1 mg tablet, 28

10539Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1119.79	37.70	Inlyta [PF]

axitinib 5 mg tablet, 28

10556N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*5186.87	37.70	Inlyta [PF]

■ **AXITINIB**

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

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

Note Special Pricing Arrangements apply.

Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have progressive disease according to the Response Evaluation Criteria In Solid Tumours (RECIST) following first-line treatment with a tyrosine kinase inhibitor, **AND**

Patient must have a WHO performance status of 2 or less, **AND**

The treatment must be the sole PBS-subsidised therapy for this condition.

Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised treatment with this drug.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

Prescribers may request an increased maximum quantity sufficient to provide up to one month's supply for patients who require dose adjustment.

axitinib 1 mg tablet, 28

10572K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*1119.79	37.70	Inlyta [PF]

axitinib 5 mg tablet, 28

10540R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*5186.87	37.70	Inlyta [PF]

■ **AZITHROMYCIN**

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

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

Restricted benefit

Trachoma

azithromycin 200 mg/5 mL oral liquid: powder for, 15 mL

8201P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	#25.51	27.04	Zithromax [PF]

azithromycin 500 mg tablet, 2

8336R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	16.06	17.23	^a APO-Azithromycin [TX] ^a Azithromycin Sandoz [SZ] ^a Terry White Chemists Azithromycin [TW]	^a Azithromycin-GA [EA] ^a Chem mart Azithromycin [CH] ^a Zithromax [PF]

■ AZITHROMYCIN

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

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

Restricted benefit

Urethritis

Clinical criteria:

The condition must be uncomplicated and due to Chlamydia trachomatis.

Restricted benefit

Cervicitis

Clinical criteria:

The condition must be uncomplicated and due to Chlamydia trachomatis.

azithromycin 500 mg tablet, 2

8200N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	16.06	17.23	^a APO-Azithromycin [TX] ^a Azithromycin Sandoz [SZ] ^a Terry White Chemists Azithromycin [TW] ^a Zitrocin [GN]	^a Azithromycin-GA [EA] ^a Chem mart Azithromycin [CH] ^a Zithromax [PF]

■ BENZTROPINE

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

10013B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	276.21	37.70	Benztropine Omega [FK]

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

10027R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	276.21	37.70	Benztropine Omega [FK]

■ BENZYLAMINE

Restricted benefit

Mucositis

Clinical criteria:

The condition must be radiation induced.

benzylamine hydrochloride 0.15% mouthwash, 500 mL

1121B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	1	..	24.19	25.36	Diffiam [IA]

■ BENZYLAMINE

Restricted benefit

Mucositis

Clinical criteria:

The condition must be radiation induced.

benzylamine hydrochloride 0.15% mouthwash, 500 mL

5032W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	±1	..	..	24.19	25.36	Diffiam [IA]

■ BICALUTAMIDE

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

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

Note Shared Care Model:

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

Authority required (STREAMLINED)

5729

Metastatic (stage D) carcinoma of the prostate

Clinical criteria:

The treatment must be in combination with GnRH (LH-RH) analogue therapy.

bicalutamide 50 mg tablet, 28

8094B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	98.40	37.70	^a APO-Bicalutamide [TX]	^a Bicalox [ER]

^a Bicalutamide AN [EA]^a Bicalutamide-GA [ED]^a Calutex [QA]^a Cosamide [AF]^a Cosudex [AP]

■ BISACODYL

Restricted benefit

Constipation

Clinical criteria:

Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

Restricted benefit

Constipation

Clinical criteria:

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

Restricted benefit

Constipation

Clinical criteria:

Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

Restricted benefit

Constipation

Clinical criteria:

Patient must be receiving palliative care.

Restricted benefit

Terminal malignant neoplasia

Restricted benefit

Anorectal congenital abnormalities

Restricted benefit

Megacolon

bisacodyl 10 mg suppository, 10

1260H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*23.04	24.21	^a Petrus Bisacodyl Suppositories [PP]
			^B 1.29	*24.33	24.21	^a Dulcolax [BY]

bisacodyl 10 mg suppository, 12

1258F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	4	..	*20.76	21.93	Petrus Bisacodyl Suppositories [PP]

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

1263L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	2	..	37.83	37.70	Bisalax [AS]

bisacodyl 5 mg tablet: enteric, 200 tablets

1259G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	17.11	18.28	Lax-Tab [AE]

■ BRINZOLAMIDE + BRIMONIDINE

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

The condition must have been inadequately controlled with monotherapy, **AND**

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.

brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL

10536M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	26.98	28.15	Simbrinza 1%/0.2% [AQ]

■ BRINZOLAMIDE + BRIMONIDINE

Note For prescribing in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

The condition must have been inadequately controlled with monotherapy, **AND**

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.

brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL

10547D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	26.98	28.15	Simbrinza 1%/0.2% [AQ]

■ CEFACLOR

Caution Serum sickness-like reactions have been reported with this drug, especially in children.

cefaclor 375 mg tablet: modified release, 10

1169M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	13.75	14.92	^a APO-Cefaclor CD [TX] ^a Cefaclor GH [GQ] ^a Karlor CD [LN] ^a Ozcef [RA]	^a Cefaclor-GA [EA] ^a Chem mart Cefaclor CD [CH] ^a Keflor CD [AF] ^a Terry White Chemists Cefaclor CD [TW]
			^B 6.26	20.01	14.92	^a Ceclor CD [AS]	

■ CIPROFLOXACIN

Authority required

Respiratory tract infection

Clinical criteria:

The condition must be proven or suspected to be caused by *Pseudomonas aeruginosa*, **AND**

Patient must be severely immunocompromised.

Authority required

Bacterial gastroenteritis

Clinical criteria:

Patient must be severely immunocompromised.

Authority required

Infection

Clinical criteria:

The condition must be proven to be due to *Pseudomonas aeruginosa* resistant to all other oral antimicrobials; OR

The condition must be proven to be due to other gram-negative bacteria resistant to all other oral antimicrobials.

Authority required

Bone or joint infection

Clinical criteria:

The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR

The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Epididymo-orchitis

Clinical criteria:

The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR

The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Prostatitis

Clinical criteria:

The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR

The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Perichondritis of the pinna

Clinical criteria:

The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR

The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

ciprofloxacin 500 mg tablet, 14

1209P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	17.98	19.15	^a APO-Ciprofloxacin [TX] ^a Cifran [RA] ^a Ciprofloxacin AN [EA] ^a Ciprofloxacin-DRLA [RZ]	^a C-Flox 500 [AL] ^a Ciprofloxacin 500 [CR] ^a Ciprofloxacin-BW [GQ] ^a Ciprofloxacin-GA [ED]

				^a Ciprofloxacin Sandoz [SZ]	^a Ciprol 500 [QA]
				^a GenRx Ciprofloxacin [GX]	^a Loxip 500 [DO]
	^b 2.93	20.91	19.15	^a Ciproxin 500 [BN]	

ciprofloxacin 750 mg tablet, 14

1210Q

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	21.82	22.99	^a APO-Ciprofloxacin [TX] ^a Cifran [RA] ^a Ciprofloxacin AN [EA] ^a Ciprofloxacin-DRLA [RZ] ^a Ciprofloxacin Sandoz [SZ] ^a GenRx Ciprofloxacin [GX]	^a C-Flox 750 [AL] ^a Ciprofloxacin 750 [CR] ^a Ciprofloxacin-BW [GQ] ^a Ciprofloxacin-GA [ED] ^a Ciprol 750 [QA] ^a Loxip 750 [DO]

■ CIPROFLOXACIN

Authority required

Respiratory tract infection

Clinical criteria:

The condition must be proven or suspected to be caused by *Pseudomonas aeruginosa*, **AND**
Patient must be severely immunocompromised.

Authority required

Bacterial gastroenteritis

Clinical criteria:

Patient must be severely immunocompromised.

Authority required

Infection

Clinical criteria:

The condition must be proven to be due to *Pseudomonas aeruginosa* resistant to all other oral antimicrobials; OR
The condition must be proven to be due to other gram-negative bacteria resistant to all other oral antimicrobials.

Authority required

Bone or joint infection

Clinical criteria:

The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR

The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Epididymo-orchitis

Clinical criteria:

The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR

The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Prostatitis

Clinical criteria:

The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR

The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Perichondritis of the pinna

Clinical criteria:

The condition must be suspected or proven to be caused by gram-negative bacteria resistant to all other appropriate antimicrobials; OR

The condition must be suspected or proven to be caused by gram-positive bacteria resistant to all other appropriate antimicrobials.

Authority required

Gonorrhoea

ciprofloxacin 250 mg tablet, 14

1208N

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	14.29	15.46	^a APO-Ciprofloxacin [TX] ^a Ciprofloxacin-DRLA [RZ] ^a Ciprol 250 [QA]	^a C-Flox 250 [AL] ^a Ciprofloxacin Sandoz [SZ] ^a GenRx Ciprofloxacin [GX]
		^b 2.10	16.39	15.46	^a Ciproxin 250 [BN]	

■ CLARITHROMYCIN

Restricted benefit

Bordetella pertussis

Restricted benefit

Atypical mycobacterial infections

clarithromycin 250 mg/5 mL oral liquid: powder for, 50 mL

9192T



Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
±1	..	..	#29.18	30.71	Klacid [GO]

▪ **DAPAGLIFLOZIN**

Note Continuing Therapy Only:

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

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

Authority required (STREAMLINED)

4983

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea, **AND**

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

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

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

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

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

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

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

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

Authority required (STREAMLINED)

4991

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with insulin, **AND**

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated.

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

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

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

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

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

Authority required (STREAMLINED)

5629

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin, **AND**

The treatment must be in combination with a sulfonylurea, **AND**

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

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

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

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

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

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

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

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

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

dapagliflozin 10 mg tablet, 28

10011X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	57.60	37.70	Forxiga [AP]

■ DAPAGLIFLOZIN + METFORMIN

Note Continuing Therapy Only:

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

Authority required (STREAMLINED)

5631

Diabetes mellitus type 2

Clinical criteria:

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

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

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

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

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

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

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

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

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

Authority required (STREAMLINED)

5739

Diabetes mellitus type 2

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

Authority required (STREAMLINED)

5798

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with a sulfonylurea, **AND**

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

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

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

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

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

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

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

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

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

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

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

Authority required (STREAMLINED)

5657

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with insulin, **AND**

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

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

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

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

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

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

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

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

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

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

10515K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.28	37.70	Xigduo XR 10/1000 [AP]

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

10516L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	58.44	37.70	Xigduo XR 10/500 [AP]

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

10510E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	60.85	37.70	Xigduo XR 5/1000 [AP]

■ DEGARELIX

Authority required (STREAMLINED)

5646

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

degarelix 80 mg injection [1 x 80 mg vial] (&) inert substance diluent [1 syringe], 1 pack

2784M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	413.75	37.70	Firmagon 80mg [FP]

■ DEGARELIX

Note No applications for increased maximum quantities and/or repeats will be authorised for the 120 mg powder for injection.

Authority required (STREAMLINED)

5786

Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate

degarelix 120 mg injection [2 x 120 mg vials] (&) inert substance diluent [2 syringes], 1 pack

2785N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	432.92	37.70	Firmagon 120mg [FP]

■ ESOMEPRAZOLE (&) CLARITHROMYCIN (&) AMOXYCILLIN

Restricted benefit

Eradication of *Helicobacter pylori*

Clinical criteria:

The condition must be associated with peptic ulcer disease.

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

8738X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	..	..	47.60	37.70	Nexium Hp7 [AP]

■ FLUCLOXACILLIN

Caution Severe cholestatic hepatitis has been reported with this drug. Significant risk factors are age, particularly greater than 55 years, and duration of treatment longer than 14 days.

flucloxacillin 1 g injection, 5 x 1 g vials

1525G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	22.43	23.60	^a Flubiclox [JU] ^a Hospira Pty Limited [HH]	^a Flucil [AS]

flucloxacillin 1 g injection, 5 x 1 g vials

5095E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	22.43	23.60	^a Flubiclox [JU] ^a Hospira Pty Limited [HH]	^a Flucil [AS]

■ FLUCONAZOLE

Note Shared Care Model:

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

Authority required (STREAMLINED)

5667

Cryptococcal meningitis

Authority required (STREAMLINED)

5752

Cryptococcal meningitis

Clinical criteria:

The treatment must be maintenance therapy, **AND**

Patient must be immunosuppressed.

Authority required (STREAMLINED)

5728

Oropharyngeal candidiasis

Clinical criteria:

Patient must be immunosuppressed.

Authority required (STREAMLINED)

5790

Oesophageal candidiasis

Clinical criteria:

Patient must be immunosuppressed.

Authority required (STREAMLINED)

5668

Oropharyngeal candidiasis

Clinical criteria:

The treatment must be for prophylaxis, **AND**

Patient must be immunosuppressed.

Authority required (STREAMLINED)

5811

Candida infections

Clinical criteria:

The condition must be serious or life-threatening.

fluconazole 100 mg capsule, 28

1472L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	38.70	37.70	^a Diflucan [PF] ^a Fluconazole Sandoz [SZ]	^a Dizole 100 [AF] ^a Ozole [RA]

fluconazole 100 mg/50 mL injection, 1 x 50 mL vial

1473M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	7	..	..	*21.63	22.80	^a Fluconazole Hexal [HX]	^a Fluconazole Sandoz [SZ]

fluconazole 200 mg capsule, 28

1475P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	65.50	37.70	^a APO-Fluconazole [TX] ^a Dizole 200 [AF] ^a Fluzole 200 [QA]	^a Diflucan [PF] ^a Fluconazole Sandoz [SZ] ^a Ozole [RA]

fluconazole 200 mg/100 mL injection, 1 x 100 mL vial

1474N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	7	..	..	*31.57	32.74	^a Fluconazole Alphapharm [AF] ^a Fluconazole Sandoz [SZ]	^a Fluconazole Hexal [HX]

fluconazole 400 mg/200 mL injection, 1 x 200 mL bag

1757L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	15.17	16.34	Fluconazole Alphapharm [AF]

fluconazole 50 mg capsule, 28

1471K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	24.95	26.12	^a Diflucan [PF] ^a Fluconazole Sandoz [SZ]	^a Dizole 50 [AF] ^a Ozole [RA]

■ **FLUCONAZOLE**

Note Shared Care Model:

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

Authority required

Cryptococcal meningitis

Clinical criteria:

Patient must be unable to take a solid dose form of fluconazole.

Authority required

Cryptococcal meningitis

Clinical criteria:

The treatment must be maintenance therapy, **AND**

Patient must be immunosuppressed, **AND**

Patient must be unable to take a solid dose form of fluconazole.

Authority required

Oropharyngeal candidiasis

Clinical criteria:

Patient must be immunosuppressed, **AND**

Patient must be unable to take a solid dose form of fluconazole.

Authority required

Oesophageal candidiasis

Clinical criteria:

Patient must be immunosuppressed, **AND**

Patient must be unable to take a solid dose form of fluconazole.

Authority required

Oropharyngeal candidiasis

Clinical criteria:

The treatment must be for prophylaxis, **AND**

Patient must be immunosuppressed, **AND**

Patient must be unable to take a solid dose form of fluconazole.

Authority required

Candida infections

Clinical criteria:

The condition must be serious or life-threatening, **AND**
 Patient must be unable to take a solid dose form of fluconazole.

fluconazole 50 mg/5 mL oral liquid: powder for, 35 mL

5446P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	#66.61	37.70	Diflucan [PF]

■ FLUTAMIDE

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

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

Note Shared Care Model:

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

Authority required (STREAMLINED)

5816

Metastatic (stage D) carcinoma of the prostate

Clinical criteria:

The treatment must be in combination with GnRH (LH-RH) analogue therapy.

flutamide 250 mg tablet, 100

1417N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	169.70	37.70	Flutamin [AF]

■ FONDAPARINUX

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

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

Note Shared Care Model:

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

Authority required (STREAMLINED)

5781

Prevention of venous thromboembolism

Treatment criteria:

Patient must be undergoing major hip surgery.

Authority required (STREAMLINED)

5808

Prevention of venous thromboembolism

Treatment criteria:

Patient must be undergoing total knee replacement.

FONDAPARINUX SODIUM Injection 2.5 mg in 0.5 mL single dose pre-filled syringe, 2

8775W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3.5	..	..	*132.47	37.70	Arixtra [AS]

■ GLYCEROL

Restricted benefit

Constipation

Clinical criteria:

Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

Restricted benefit

Constipation

Clinical criteria:

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

Restricted benefit

Constipation

Clinical criteria:

Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

Restricted benefit

Constipation

Clinical criteria:

Patient must be receiving palliative care.

Restricted benefit

Terminal malignant neoplasia

Restricted benefit

Anorectal congenital abnormalities

Restricted benefit

Megacolon

glycerol 1.4 g suppository, 12

2556M

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
3	5	..	*23.28	24.45	Petrus Pharmaceuticals Pty Ltd [PP]

glycerol 2.8 g suppository, 12

2557N

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
3	5	..	*23.79	24.96	Petrus Pharmaceuticals Pty Ltd [PP]

glycerol 700 mg suppository, 12

2555L

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
3	5	..	*22.89	24.06	Petrus Pharmaceuticals Pty Ltd [PP]

■ **HYDROXYCHLOROQUINE**

Note Shared Care Model:

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

hydroxychloroquine sulfate 200 mg tablet, 100

1512N

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	30.84	32.01	^a APO- Hydroxychloroquine [TX] ^a Hequinel [QA] ^a Hydroxychloroquine AN [EA] ^a Hydroxychloroquine RBX [RA] ^a Terry White Chemists Hydroxychloroquine [TW]	^a Chem mart Hydroxychloroquine [CH] ^a Hydroxychloroquine Actavis [ED] ^a Hydroxychloroquine GH [GQ] ^a Plaquenil [SW]

■ **IDARUBICIN**

Restricted benefit

Acute myelogenous leukaemia (AML)

idarubicin hydrochloride 10 mg capsule, 1

2448W

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
3	..	..	*489.84	37.70	Zavedos [PF]

idarubicin hydrochloride 5 mg capsule, 1

2446R

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
3	..	..	*305.94	37.70	Zavedos [PF]

■ **INDACATEROL + GLYCOPYRRONIUM**

Note The treatment must not be used in combination with an ICS/LABA, or LABA or LABA monotherapy.

Note A LABA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, eformoterol or vilanterol.

Note This product is not PBS-subsidised for the treatment of asthma.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Authority required (STREAMLINED)

5763

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

Patient must have been stabilised on a combination of a long acting muscarinic antagonist and long acting beta-2 agonist.

indacaterol 110 microgram + glycopyrronium 50 microgram inhalation: powder for, 30 capsules

10156M

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	91.89	37.70	ultibro breezhaler 110/50 [NV]

■ **ITRACONAZOLE**

Note Shared Care Model:

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

Authority required (STREAMLINED)**5698**

Systemic aspergillosis

Authority required (STREAMLINED)**5699**

Systemic sporotrichosis

Authority required (STREAMLINED)**5793**

Systemic histoplasmosis

Authority required (STREAMLINED)**5760**

Disseminated pulmonary histoplasmosis infection

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

Patient must have HIV infection.

Authority required (STREAMLINED)**5700**

Chronic pulmonary histoplasmosis infection

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

Patient must have HIV infection.

Authority required (STREAMLINED)**5728**

Oropharyngeal candidiasis

Clinical criteria:

Patient must be immunosuppressed.

Authority required (STREAMLINED)**5790**

Oesophageal candidiasis

Clinical criteria:

Patient must be immunosuppressed.

itraconazole 100 mg capsule, 60

8196J

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	234.27	37.70	Sporanox [JC]

■ LANSOPRAZOLE**Restricted benefit**

Gastro-oesophageal reflux disease

Restricted benefit

Scleroderma oesophagus

lansoprazole 15 mg capsule: enteric, 30

8198L

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	16.67	17.84	Zopral [AF]

lansoprazole 15 mg tablet: orally disintegrating, 28 tablets

9331D

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	16.23	17.40	^a APO-Lansoprazole ODT [TX]	^a Lansoprazole ODT GH [GQ]
					^a Zopral ODT [AF]	
		^b 4.00	20.23	17.40	^a Zoton FasTabs [PF]	

■ LANSOPRAZOLE

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

Restricted benefit

Gastro-oesophageal reflux disease

Restricted benefit

Scleroderma oesophagus

lansoprazole 30 mg capsule: enteric, 28

2241Y

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	20.85	22.02	^a APO-Lansoprazole [TX]	^a Lanzopran [RA]
					^a Zopral [AF]	

lansoprazole 30 mg tablet: orally disintegrating, 28 tablets

9478W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	20.85	22.02	^a APO-Lansoprazole ODT [TX] ^a Zopral ODT [AF]	^a Lansoprazole ODT GH [GQ]
			^B 4.00	24.85	22.02	^a Zoton FasTabs [PF]	

■ LANSOPRAZOLE

Note Helicobacter pylori eradication therapy should be considered.

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

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

Restricted benefit

Peptic ulcer

Treatment Phase: Initial treatment

lansoprazole 30 mg capsule: enteric, 28

2240X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	20.85	22.02	^a APO-Lansoprazole [TX] ^a Zopral [AF]	^a Lanzopran [RA]

lansoprazole 30 mg tablet: orally disintegrating, 28 tablets

9477T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	20.85	22.02	^a APO-Lansoprazole ODT [TX] ^a Zopral ODT [AF]	^a Lansoprazole ODT GH [GQ]
			^B 4.00	24.85	22.02	^a Zoton FasTabs [PF]	

■ LEFLUNOMIDE

Caution Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

Authority required (STREAMLINED)

5766

Severe active psoriatic arthritis

Clinical criteria:

Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR

Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, **AND**

The treatment must be initiated by a physician.

leflunomide 10 mg tablet, 30

5449T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	48.10	37.70	^a Arabloc [AV] ^a Leflunomide Sandoz [SZ]	^a Arava [SW]

leflunomide 20 mg tablet, 30

5450W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	67.77	37.70	^a Arabloc [AV] ^a Leflunomide Sandoz [SZ]	^a Arava [SW]

■ LEFLUNOMIDE

Caution Leflunomide is a category X drug and must not be given to pregnant women. Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

Authority required (STREAMLINED)

5681

Severe active rheumatoid arthritis

Clinical criteria:

Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR

Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate, **AND**

The treatment must be initiated by a physician.

leflunomide 10 mg tablet, 30

8374R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	48.10	37.70	^a APO-Leflunomide [TX] ^a Arava [SW] ^a Leflunomide-GA [ED] ^a Leflunomide Sandoz [SZ]	^a Arabloc [AV] ^a Leflunomide AN [EA] ^a Leflunomide GH [GQ] ^a Lunava 10 [ZP]

leflunomide 20 mg tablet, 30

8375T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	67.77	37.70	^a APO-Leflunomide [TX] ^a Arava [SW] ^a Leflunomide-GA [ED] ^a Leflunomide Sandoz [SZ]	^a Arabloc [AV] ^a Leflunomide AN [EA] ^a Leflunomide GH [GQ] ^a Lunava 20 [ZP]

LEUPRORELIN**Authority required (STREAMLINED)****5646**

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

leuporelin acetate 22.5 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack

8708H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1101.16	37.70	Eligard 3 month [TL]

leuporelin acetate 22.5 mg injection: modified release [1 x 22.5 mg syringe] (&) inert substance diluent [1 x 2 mL syringe], 1 pack

8876E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1101.16	37.70	Lucrin Depot 3 Month PDS [VE]

leuporelin acetate 30 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack

8709J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1442.09	37.70	Eligard 4 month [TL]

leuporelin acetate 30 mg injection: modified release [1 x 30 mg syringe] (&) inert substance diluent [1 x 2 mL syringe], 1 pack

8877F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1442.09	37.70	Lucrin Depot 4 Month PDS [VE]

leuporelin acetate 45 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack

8859G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	2123.34	37.70	Eligard 6 month [TL]

leuporelin acetate 7.5 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack

8707G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	413.75	37.70	Eligard 1 month [TL]

leuporelin acetate 7.5 mg injection: modified release [1 x 7.5 mg syringe] (&) inert substance diluent [1 x 2 mL syringe], 1 pack

8875D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	413.75	37.70	Lucrin Depot 7.5mg PDS [VE]

LEUPRORELIN**Authority required**

Central precocious puberty

Treatment Phase: Initial treatment

Population criteria:Patient must be aged 10 years or younger (girls) or 11 years or younger (boys), **AND**

Patient must have had onset of signs or symptoms of central precocious puberty prior to the age of 8 years (girls) or 9 years (boys).

Treatment criteria:

Must be treated by a paediatric endocrinologist; OR

Must be treated by an endocrinologist specialising in paediatrics.

Authority required

Central precocious puberty

Treatment Phase: Initial - grandfather

Clinical criteria:

Patient must have received treatment with a gonadotropin releasing hormone analogue (GnRHa) for this condition prior to 1 May 2015.

Treatment criteria:

Must be treated by a paediatric endocrinologist; OR

Must be treated by an endocrinologist specialising in paediatrics.

leuporelin acetate 30 mg injection: modified release [1 syringe] (&) inert substance diluent [1 syringe], 1 pack

10256T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	1	..	1442.09	37.70	Lucrin Depot Paediatric 30 mg PDS [VE]

▪ MEDROXYPROGESTERONE**Restricted benefit**

Advanced breast cancer

Clinical criteria:

The condition must be hormone receptor positive.

medroxyprogesterone acetate 500 mg tablet, 30

2728N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	135.53	37.70	Provera [PF]

▪ MEDROXYPROGESTERONE**Restricted benefit**

Breast cancer

Clinical criteria:

The condition must be hormone receptor positive.

Restricted benefit

Endometrial cancer

medroxyprogesterone acetate 100 mg tablet, 100

2725K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	98.05	37.70	Provera [PF]

medroxyprogesterone acetate 200 mg tablet, 60

2316X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	110.11	37.70	Provera [PF]

medroxyprogesterone acetate 250 mg tablet, 60

2727M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	135.53	37.70	Provera [PF]

▪ METHOTREXATE**Restricted benefit**

Patients requiring doses greater than 20 mg per week

methotrexate 10 mg tablet, 50

1623K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	50.74	37.70	Methoblastin [PF]

▪ METHOTREXATE

Note For item codes 2395C and 1818Q, pharmaceutical benefits that have the form injection 50 mg in 2 mL are equivalent for the purposes of substitution.

METHOTREXATE Injection 50 mg in 2 mL, 1

1818Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	5	..	*50.33	37.70	^a Methaccord [EA]	^a Methotrexate MYX [YN]

methotrexate 50 mg/2 mL injection, 5 x 2 mL vials

2395C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	50.31	37.70	^a Hospira Pty Limited [HH]

▪ METRONIDAZOLE**Restricted benefit**

Anaerobic infections

metronidazole 400 mg tablet, 21

1621H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	13.40	14.57	^a Metrogyl 400 [AF]	^a Metronide 400 [AV]
			^B 2.00	15.40	14.57	^a Flagyl [SW]	

▪ METRONIDAZOLE**Restricted benefit**

Anaerobic infections

metronidazole 400 mg tablet, 21

5155H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	13.40	14.57	^a Metrogyl 400 [AF]	^a Metronide 400 [AV]
			^b 2.00	15.40	14.57	^a Flagyl [SW]	

■ NILUTAMIDE**Note Shared Care Model:**

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

Authority required (STREAMLINED)**5785**

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

Clinical criteria:

The treatment must be in combination with GnRH (LH-RH) analogue therapy.

Authority required (STREAMLINED)**5647**

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

Clinical criteria:

The treatment must be in conjunction with surgical orchidectomy.

nilutamide 150 mg tablet, 30

8131Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	223.68	37.70	Anandron [SW]

■ NITRAZEPAM**Note Continuing Therapy Only:**

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

Authority required

Myoclonic epilepsy

Authority required

Malignant neoplasia (late stage)

Authority required

Benzodiazepine dependence

Clinical criteria:

Patient must be receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities, **AND**

Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

Authority required

Benzodiazepine dependence

Clinical criteria:

Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult, **AND**

Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

nitrazepam 5 mg tablet, 25

2732T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*13.65	14.82	^a Alodorm [AF]
			^b 2.48	*16.13	14.82	^a Mogadon [IA]

■ NORFLOXACIN**Authority required**

Acute bacterial enterocolitis

Authority required

Complicated urinary tract infection

norfloxacin 400 mg tablet, 14

3010K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	14.44	15.61	^a GenRx Norfloxacin [GX]	^a Norfloxacin-GA [GN]
						^a Norfloxacin Sandoz [SZ]	^a Nufloxib [AF]
						^a Roxin [QA]	

■ OMEPRAZOLE

Restricted benefit

Gastro-oesophageal reflux disease

Restricted benefit

Scleroderma oesophagus

Restricted benefit

Zollinger-Ellison syndrome

omeprazole 10 mg tablet: enteric, 30 tablets

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

■ ONDANSETRON

Authority required (STREAMLINED)

4102

Nausea and vomiting

Clinical criteria:

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

ondansetron 4 mg tablet, 10

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

ondansetron 4 mg/5 mL oral liquid, 50 mL

8233H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	1	..	97.27	37.70	Zofran syrup 50 mL [AS]

ondansetron 8 mg tablet, 10

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

■ ONDANSETRON

Authority required (STREAMLINED)

4092

Nausea and vomiting

Clinical criteria:

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

ondansetron 4 mg/2 mL injection, 1 x 2 mL ampoule

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

ondansetron 8 mg/4 mL injection, 1 x 4 mL ampoule

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

■ ONDANSETRON

Restricted benefit

Nausea and vomiting

Clinical criteria:

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

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

ondansetron 4 mg tablet, 4

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

ondansetron 8 mg tablet, 4

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

■ ONDANSETRON**Restricted benefit**

Nausea and vomiting

Clinical criteria:

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

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

ondansetron 4 mg/2 mL injection, 1 x 2 mL ampoule

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

ondansetron 8 mg/4 mL injection, 1 x 4 mL ampoule

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

■ ONDANSETRON**Restricted benefit**

Nausea and vomiting

Clinical criteria:

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

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

ondansetron 4 mg/5 mL oral liquid, 50 mL

9441X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	..	..	97.27	37.70	Zofran syrup 50 mL [AS]

■ ONDANSETRON

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

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

Restricted benefit

Nausea and vomiting

Clinical criteria:

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

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

ONDANSETRON Tablet (orally disintegrating) 4 mg, 4

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

ONDANSETRON Tablet (orally disintegrating) 8 mg, 4

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

ondansetron 4 mg wafer, 4

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

ondansetron 8 mg wafer, 4

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

■ ONDANSETRON

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

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

Authority required (STREAMLINED)

5777

Nausea and vomiting

Clinical criteria:

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

ONDANSETRON Tablet (orally disintegrating) 4 mg, 10

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

ONDANSETRON Tablet (orally disintegrating) 8 mg, 10

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

ondansetron 4 mg wafer, 10

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

ondansetron 8 mg wafer, 10

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

■ PALONOSETRON

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

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

Restricted benefit

Nausea and vomiting

Clinical criteria:

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

palonosetron 250 microgram/5 mL injection, 1 x 5 mL vial

5295Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	47.36	37.70	Aloxi [TS]

■ PANCREATIC EXTRACT

Note Continuing Therapy Only:

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

pancreatic extract 10 000 international units capsule: modified release, 100 capsules

8020D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	5	10	..	*171.58	37.70	Creon 10,000 [GO]

pancreatic extract 25 000 international units capsule: modified release, 100 capsules

8021E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	10	..	*138.91	37.70	Creon 25,000 [GO]

pancreatic extract 40 000 international units capsule: modified release, 100 capsules

9412J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	10	..	*216.85	37.70	Creon 40,000 [GO]

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

5453B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	10	..	*133.47	37.70	Creon Micro [GO]

■ PANCREATIC EXTRACT

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

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

Restricted benefit

Cystic fibrosis

Clinical criteria:

Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

pancreatic extract 10 000 international units capsule: modified release, 100 capsules

9226N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	21	..	*171.58	37.70	Creon 10,000 [GO]

pancreatic extract 25 000 international units capsule: modified release, 100 capsules

9227P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	21	..	*138.91	37.70	Creon 25,000 [GO]

pancreatic extract 40 000 international units capsule: modified release, 100 capsules

9413K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	21	..	*216.85	37.70	Creon 40,000 [GO]

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

5454C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	21	..	*133.47	37.70	Creon Micro [GO]

■ PANCRELIPASE

Note Continuing Therapy Only:

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

pancrelipase 25 000 units capsule, 100

8366H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	10	..	*129.95	37.70	Panzytrat 25000 [TM]

■ PANCRELIPASE

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

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

Restricted benefit

Cystic fibrosis

Clinical criteria:

Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

pancrelipase 25 000 units capsule, 100

9229R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	21	..	*129.95	37.70	Panzytrat 25000 [TM]

■ PARAFFIN

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

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

Restricted benefit

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

paraffin 1 g/g eye ointment, 3.5 g

9217D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	11	..	*23.31	24.48	Poly Visc [IQ]

■ PHENOXYMETHYLPENICILLIN

Restricted benefit

Recurrent streptococcal infections (including rheumatic fever)

Clinical criteria:

The treatment must be for prophylaxis.

phenoxymethylpenicillin 250 mg capsule, 50

1705R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.54	15.71	LPV [IA] ^a Cilicaine VK [FM]	^a Cilopen VK [GN]

phenoxymethylpenicillin 250 mg tablet, 25

1703P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*14.69	15.86	Abbocillin-VK Filmtab [QA]

■ POSACONAZOLE

Note Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

Note Shared Care Model:

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

Authority required

Invasive aspergillosis

Clinical criteria:

Patient must be unable to tolerate alternative therapy; OR
Patient must have disease refractory to alternative therapy.

Authority required

Fungal infection

Clinical criteria:

The condition must be fusariosis; OR
The condition must be zygomycosis; OR
The condition must be coccidioidomycosis; OR
The condition must be chromoblastomycosis; OR
The condition must be mycetoma, **AND**
Patient must be unable to tolerate alternative therapy; OR
Patient must have disease refractory to alternative therapy.

Authority required

Prophylaxis of invasive fungal infections including both yeasts and moulds

Clinical criteria:

Patient must be considered at high risk of developing an invasive fungal infection due to anticipated neutropenia (an absolute neutrophil count less than 500 cells per cubic millimetre), for at least 10 days whilst receiving chemotherapy for acute myeloid leukaemia or myelodysplastic syndrome; OR
Patient must be considered at high risk of developing an invasive fungal infection due to having acute graft versus host disease (GVHD) grade II, III or IV, or extensive chronic GVHD, and receiving intensive immunosuppressive therapy after allogeneic haematopoietic stem cell transplant.

No more than 6 months therapy per episode will be PBS-subsidised

posaconazole 40 mg/mL oral liquid, 105 mL

9360P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	727.46	37.70	Noxafil [MK]

■ PRAZIQUANTEL

Authority required (STREAMLINED)

5659

Schistosomiasis

praziquantel 600 mg tablet, 8

9447F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	40.36	37.70	Biltricide [BN]

■ QUETIAPINE

Note Shared Care Model:

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

Authority required (STREAMLINED)

4246

Schizophrenia

Authority required (STREAMLINED)

5611

Acute mania

Clinical criteria:

The condition must be associated with bipolar I disorder, **AND**
The treatment must be as monotherapy, **AND**
The treatment must be limited to up to 6 months per episode.

Authority required (STREAMLINED)

5639

Bipolar I disorder

Clinical criteria:

The treatment must be maintenance therapy.

quetiapine 100 mg tablet, 90

8457D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	47.89	37.70	^a APO-Quetiapine [TX] ^a Delucon 100 [DO] ^a Pharmacor Quetiapine 100 [CR] ^a Quetia 100 [FM] ^a Quetiapine Actavis 100 [ED] ^a Quetiapine-DRLA [RZ] ^a Quetiapine GH 100 [GQ] ^a Quetiapine Sandoz [SZ] ^a Seroquel [AP] ^a Terry White Chemists Quetiapine [TW]	^a Chem mart Quetiapine [CH] ^a Kaptan [ER] ^a Pharmacy Choice Quetiapine [RI] ^a Quetiaccord [EF] ^a Quetiapine AN [EA] ^a Quetiapine-GA [GN] ^a Quetiapine RBX [RA] ^a Seronia 100 [QA] ^a Syquet [AF]

quetiapine 150 mg tablet: modified release, 60 tablets

5458G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	47.89	37.70	Seroquel XR [AP]

quetiapine 200 mg tablet, 60

8458E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	61.48	37.70	^a APO-Quetiapine [TX] ^a Delucon 200 [DO] ^a Pharmacor Quetiapine 200 [CR] ^a Quetia 200 [FM] ^a Quetiapine Actavis 200 [ED] ^a Quetiapine-DRLA [RZ] ^a Quetiapine GH 200 [GQ] ^a Quetiapine Sandoz [SZ] ^a Seroquel [AP] ^a Terry White Chemists Quetiapine [TW]	^a Chem mart Quetiapine [CH] ^a Kaptan [ER] ^a Pharmacy Choice Quetiapine [RI] ^a Quetiaccord [EF] ^a Quetiapine AN [EA] ^a Quetiapine-GA [GN] ^a Quetiapine RBX [RA] ^a Seronia 200 [QA] ^a Syquet [AF]

quetiapine 200 mg tablet: modified release, 60 tablets

9203J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	61.48	37.70	Seroquel XR [AP]

quetiapine 300 mg tablet, 60

8580N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	85.33	37.70	^a APO-Quetiapine [TX] ^a Delucon 300 [DO] ^a Pharmacor Quetiapine 300 [CR] ^a Quetia 300 [FM] ^a Quetiapine Actavis 300 [ED] ^a Quetiapine-DRLA [RZ] ^a Quetiapine GH 300 [GQ] ^a Quetiapine Sandoz [SZ] ^a Seroquel [AP] ^a Terry White Chemists Quetiapine [TW]	^a Chem mart Quetiapine [CH] ^a Kaptan [ER] ^a Pharmacy Choice Quetiapine [RI] ^a Quetiaccord [EF] ^a Quetiapine AN [EA] ^a Quetiapine-GA [GN] ^a Quetiapine RBX [RA] ^a Seronia 300 [QA] ^a Syquet [AF]

quetiapine 300 mg tablet: modified release, 60 tablets

9204K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	85.33	37.70	Seroquel XR [AP]

quetiapine 400 mg tablet: modified release, 60 tablets

9205L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	112.53	37.70	Seroquel XR [AP]

quetiapine 50 mg tablet: modified release, 60 tablets

9202H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	36.90	37.70	Seroquel XR [AP]

■ QUININE

Caution Severe thrombocytopenia has been reported with this drug.

Authority required (STREAMLINED)

5633

Malaria

quinine sulfate 300 mg tablet, 50

1975Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	17.13	18.30	Quinate [AS]

■ RABEPRAZOLE

Restricted benefit

Gastro-oesophageal reflux disease

Restricted benefit

Scleroderma oesophagus

rabeprazole sodium 10 mg tablet: enteric, 28

8507R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.74	17.91	^a APO-Rabeprazole [TX] ^a Parbezol [QA] ^a Parzol 10 [ZP] ^a Rabeprazole AN [EA] ^a Rabeprazole-GA [GN] ^a Rabeprazole Sandoz [SZ] ^a Terry White Chemists Rabeprazole [TW]	^a Chem mart Rabeprazole [CH] ^a Pariet [JC] ^a Prabez [AF] ^a Rabeprazole-DRLA [RZ] ^a Rabeprazole generichealth [GQ] ^a Razit 10 [DO]

rabeprazole sodium 20 mg tablet: enteric, 30

8508T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.74	17.91	^a APO-Rabeprazole [TX] ^a Parbezol [QA] ^a Parzol 20 [ZP] ^a Rabeprazole Actavis 20 [ED] ^a Rabeprazole-DRLA [RZ] ^a Rabeprazole Sandoz [SZ] ^a Razit 20 [DO] ^a Zabep [AL]	^a Chem mart Rabeprazole [CH] ^a Pariet [JC] ^a Prabez [AF] ^a Rabeprazole AN [EA] ^a Rabeprazole generichealth [GQ] ^a Rabeprazole SUN [RN] ^a Terry White Chemists Rabeprazole [TW]

■ RABEPRAZOLE

Note Helicobacter pylori eradication therapy should be considered.

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

Restricted benefit

Peptic ulcer

Treatment Phase: Initial treatment

rabeprazole sodium 20 mg tablet: enteric, 30

8509W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	16.74	17.91	^a APO-Rabeprazole [TX] ^a Parbezol [QA] ^a Parzol 20 [ZP] ^a Rabeprazole Actavis 20 [ED] ^a Rabeprazole-DRLA [RZ] ^a Rabeprazole Sandoz [SZ] ^a Razit 20 [DO] ^a Zabep [AL]	^a Chem mart Rabeprazole [CH] ^a Pariet [JC] ^a Prabez [AF] ^a Rabeprazole AN [EA] ^a Rabeprazole generichealth [GQ] ^a Rabeprazole SUN [RN] ^a Terry White Chemists Rabeprazole [TW]

■ RETEPLASE

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical

practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted benefit

Acute myocardial infarction

Clinical criteria:

The treatment must be administered within 6 hours of the onset of attack.

reteplase 10 units (17.4 mg) injection [2 x 10 units vials] (&) inert substance diluent [2 x 10 mL syringes], 1 pack

8253J



Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
#1	..	..	2064.33	37.70	Rapilysin 10 U [GN]

▪ **RHAMNUS FRANGULA + STERCULIA**

Restricted benefit

Constipation

Clinical criteria:

Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

Restricted benefit

Constipation

Clinical criteria:

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

Restricted benefit

Constipation

Clinical criteria:

Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

Restricted benefit

Constipation

Clinical criteria:

Patient must be receiving palliative care.

Restricted benefit

Terminal malignant neoplasia

Restricted benefit

Anorectal congenital abnormalities

Restricted benefit

Megacolon

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

1104D



Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
#1	1	..	27.77	28.94	Normacol Plus [NE]

▪ **RIVASTIGMINE**

Note Continuing Therapy Only:

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

Authority required (STREAMLINED)

4219

Mild to moderately severe Alzheimer disease

Treatment Phase: Continuing

Clinical criteria:

Patient must have received six months of sole PBS-subsidised initial therapy with this drug, **AND**

Patient must demonstrate a clinically meaningful response to the initial treatment, **AND**

The treatment must be the sole PBS-subsidised therapy for this condition.

Prior to continuing treatment, a comprehensive assessment must be undertaken and documented, involving the patient, the patient's family or carer and the treating physician to establish agreement that treatment is continuing to produce worthwhile benefit.

Treatment should cease if there is no agreement of benefit as there is always the possibility of harm from unnecessary use.

Re-assessments for a clinically meaningful response are to be undertaken and documented every six months.

Clinically meaningful response to treatment is demonstrated in the following areas:

Patient's quality of life including but not limited to level of independence and happiness;

Patient's cognitive function including but not limited to memory, recognition and interest in environment;

Patient's behavioural symptoms, including but not limited to hallucination, delusions, anxiety, marked agitation or associated aggressive behaviour.

rivastigmine 13.3 mg/24 hours patch, 30

10538P

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	97.51	37.70	Exelon Patch 15 [NV]

■ RIVASTIGMINE

Note Continuing Therapy Only:

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

Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 10 or more, **AND**

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND** The treatment must be the sole PBS-subsidised therapy for this condition.

The authority application must include the result of the baseline MMSE or SMMSE. If this score is 25 - 30 points, the result of a baseline Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog) may also be specified.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

Authority required

Mild to moderately severe Alzheimer disease

Treatment Phase: Initial

Clinical criteria:

Patient must have a baseline Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE) score of 9 or less, **AND**

The condition must be confirmed by, or in consultation with, a specialist/consultant physician (including a psychiatrist), **AND** The treatment must be the sole PBS-subsidised therapy for this condition.

A patient who is unable to register a score of 10 or more for reasons other than their Alzheimer disease, as specified below. Such patients will need to be assessed using the Clinicians Interview Based Impression of Severity (CIBIS) scale. The authority application must include the result of the baseline (S)MMSE and specify to which group(s) (see below) the patient belongs.

Patients who qualify under this criterion are from 1 or more of the following groups:

- (1) Unable to communicate adequately because of lack of competence in English, in people of non-English speaking background;
- (2) Limited education, as defined by less than 6 years of education, or who are illiterate or innumerate;
- (3) Aboriginal or Torres Strait Islanders who, by virtue of cultural factors, are unable to complete an (S)MMSE test;
- (4) Intellectual (developmental or acquired) disability, eg Down's syndrome;
- (5) Significant sensory impairment despite best correction, which precludes completion of an (S)MMSE test;
- (6) Prominent dysphasia, out of proportion to other cognitive and functional impairment.

The application must be made in writing, but initial supply may be sought by telephone.

For telephone applications, up to a maximum of 2 months' initial therapy will be authorised. This telephone application must be followed by a written authority application for no more than 1 month's therapy and sufficient repeats to complete a maximum of up to 6 months' initial treatment.

For written applications where no prior telephone approval has been issued, up to a maximum of 1 month's therapy plus 5 repeats will be authorised.

rivastigmine 13.3 mg/24 hours patch, 30

10541T

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	97.51	37.70	Exelon Patch 15 [NV]

■ RIZATRIPTAN

Caution Selective serotonin (5HT₁) agonists are contraindicated in patients with known or suspected coronary artery disease. The drug should not be used within 24 hours of ergotamine or dihydroergotamine use.

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

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

Note Continuing Therapy Only:

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

Note Pharmaceutical benefits that have the form rizatriptan wafer 10 mg (as benzoate) and pharmaceutical benefits that have the form rizatriptan tablet (orally disintegrating) 10 mg (as benzoate) are equivalent for the purposes of substitution.

Restricted benefit

Migraine attack

Clinical criteria:

The condition must have usually failed to respond to analgesics in the past.

rizatriptan 10 mg tablet: orally disintegrating, 2

10551H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*24.09	25.26	^a Rizatriptan AN ODT [EA]

rizatriptan 10 mg wafer, 2

9313E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*24.09	25.26	^a Maxalt [MK]	^a Rizatriptan Wafers-10mg [FR]

■ SAXAGLIPTIN**Authority required (STREAMLINED)****5623**

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea, **AND**

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

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

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

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

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

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

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

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

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.**Authority required (STREAMLINED)****5679**

Diabetes mellitus type 2

Clinical criteria:The treatment must be in combination with metformin, **AND**The treatment must be in combination with a sulfonylurea, **AND**

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

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

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

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

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

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

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

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

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

saxagliptin 2.5 mg tablet, 28

10128C

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	58.09	37.70	Onglyza [AP]

saxagliptin 5 mg tablet, 28

8983T

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	58.09	37.70	Onglyza [AP]

■ SAXAGLIPTIN + METFORMIN

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

Authority required (STREAMLINED)

5761

Diabetes mellitus type 2

Clinical criteria:

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

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

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

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

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

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

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

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

Authority required (STREAMLINED)

5762

Diabetes mellitus type 2

Treatment Phase: Continuing

Clinical criteria:

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

Authority required (STREAMLINED)

5705

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with a sulfonylurea, **AND**

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

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

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

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

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

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

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

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

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

saxagliptin 2.5 mg + metformin hydrochloride 1 g tablet: modified release, 56

10048W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	61.34	37.70	Kombiglyze XR 2.5/1000 [AP]

saxagliptin 5 mg + metformin hydrochloride 1 g tablet: modified release, 28

10051B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.77	37.70	Kombiglyze XR 5/1000 [AP]

saxagliptin 5 mg + metformin hydrochloride 500 mg tablet: modified release, 28

10055F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	58.93	37.70	Kombiglyze XR 5/500 [AP]

■ SITAGLIPTIN**Authority required (STREAMLINED)****5655**

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea, **AND**

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

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

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

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

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

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

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

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

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

Authority required (STREAMLINED)**5679**

Diabetes mellitus type 2

Clinical criteria:The treatment must be in combination with metformin, **AND**The treatment must be in combination with a sulfonylurea, **AND**

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

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

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

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

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

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

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

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

Note This drug is not PBS-subsidised for use as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.**Note** PBS subsidised dual oral therapy does not include concomitant use of a combination of: a gliptin, a glitazone or an SGLT2 inhibitor.

sitagliptin 100 mg tablet, 28

9182G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	58.09	37.70	Januvia [MK]

sitagliptin 25 mg tablet, 28

9180E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	58.09	37.70	Januvia [MK]

sitagliptin 50 mg tablet, 28

9181F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	58.09	37.70	Januvia [MK]

■ SITAGLIPTIN + METFORMIN

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

Authority required (STREAMLINED)**5761**

Diabetes mellitus type 2

Clinical criteria:

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

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

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

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

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

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

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

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

Authority required (STREAMLINED)**5709**

Diabetes mellitus type 2

Treatment Phase: Continuing

Clinical criteria:

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

Authority required (STREAMLINED)**5705**

Diabetes mellitus type 2

Clinical criteria:

The treatment must be in combination with a sulfonylurea, **AND**

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

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

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

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

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

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

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

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

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

sitagliptin 100 mg + metformin hydrochloride 1 g tablet: modified release, 28

10089B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.77	37.70	Janumet XR [MK]

sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56

9451K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	61.34	37.70	Janumet [MK]

sitagliptin 50 mg + metformin hydrochloride 1 g tablet: modified release, 56

10090C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	61.34	37.70	Janumet XR [MK]

sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56

9449H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.77	37.70	Janumet [MK]

sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56

9450J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	60.89	37.70	Janumet [MK]

▪ SORBITOL + CITRATE + LAURYL SULFOACETATE SODIUM**Restricted benefit**

Constipation

Clinical criteria:

Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

Restricted benefit

Constipation

Clinical criteria:

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

Restricted benefit

Constipation

Clinical criteria:

Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

Restricted benefit

Constipation

Clinical criteria:

Patient must be receiving palliative care.

Restricted benefit

Terminal malignant neoplasia

Restricted benefit

Anorectal congenital abnormalities

Restricted benefit

Megacolon

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

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

▪ SOTALOL**Note Shared Care Model:**

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

Restricted benefit

Severe cardiac arrhythmias

sotalol hydrochloride 160 mg tablet, 60

2043M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.29	19.46	^a APO-Sotalol [TX]	^a Cardol [AF]
						^a Solavert [QA]	^a Sotalol Sandoz [SZ]
			^b 2.89	21.18	19.46	^a Sotacor [FM]	

sotalol hydrochloride 80 mg tablet, 60

8398B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.09	15.26	^a APO-Sotalol [TX] ^a Solavert [QA]	^a GenRx Sotalol [GX] ^a Sotalol Sandoz [SZ]
			^b 2.88	16.97	15.26	^a Sotacor [FM]	

■ TAMOXIFEN

Note This drug is not PBS-subsidised for primary prevention of breast cancer.

Note Shared Care Model:

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

Restricted benefit

Breast cancer

Clinical criteria:

The condition must be hormone receptor positive.

tamoxifen 10 mg tablet, 60

2109B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	23.48	24.65	Genox 10 [AF]

■ TAMOXIFEN

Note This drug is not PBS-subsidised for primary prevention of breast cancer.

Note For item codes 2110C and 1880Y, pharmaceutical benefits that have the form tablet 20 mg (base) are equivalent for the purposes of substitution.

Note Shared Care Model:

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

Restricted benefit

Breast cancer

Clinical criteria:

The condition must be hormone receptor positive.

tamoxifen 20 mg tablet, 30

1880Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	^b 2.20	*35.27	34.24	^a Nolvadex-D [AP]

tamoxifen 20 mg tablet, 60

2110C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	33.06	34.23	^a Genox 20 [AF] ^a Tamosin [QA] ^a Tamoxifen Sandoz [SZ]	^a GenRx Tamoxifen [GX] ^a Tamoxen 20 mg [EA]

■ TEMAZEPAM

Note Authorities for increased maximum quantities and/or repeats will not be granted except as detailed under the 'Authority required' listing of temazepam.

temazepam 10 mg tablet, 25

2089Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	11.23	12.40	^a APO-Temazepam [TX] ^a Temtabs [FM]	^a Temaze [AF]
			^b 3.48	14.71	12.40	^a Normison [QA]	

■ TEMAZEPAM**Note Continuing Therapy Only:**

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

Authority required

Malignant neoplasia (late stage)

Authority required

Benzodiazepine dependence

Clinical criteria:

Patient must be receiving long-term nursing care on account of age, infirmity or other condition in hospitals, nursing homes or residential facilities, **AND**

Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

Authority required

Benzodiazepine dependence

Clinical criteria:

Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult, **AND**

Patient must have demonstrated, within the past 6 months, benzodiazepine dependence by an unsuccessful attempt at gradual withdrawal.

temazepam 10 mg tablet, 25

2088X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*12.05	13.22	^a APO-Temazepam [TX]	^a Temaze [AF]
			^B 6.96	*19.01	13.22	^a Temtabs [FM]	
						^a Normison [QA]	

▪ **TENECTEPLASE**

Note Shared Care Model:

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

Restricted benefit

Acute myocardial infarction

Clinical criteria:

The treatment must be administered within 12 hours of onset of attack.

tenecteplase 10 000 international units (50 mg) injection [1 x 50 mg vial] (&) inert substance diluent [1 x 10 mL syringe], 1 pack

8527T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	2054.08	37.70	Metalyse [BY]

tenecteplase 8000 international units (40 mg) injection [1 x 40 mg vial] (&) inert substance diluent [1 x 8 mL syringe], 1 pack

8526R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	1954.41	37.70	Metalyse [BY]

▪ **TICAGRELOR**

Note Shared Care Model:

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

Authority required (STREAMLINED)

5746

Acute coronary syndrome (myocardial infarction or unstable angina)

Clinical criteria:

The treatment must be in combination with aspirin.

TICAGRELOR Tablet 90 mg, 56

1418P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	140.04	37.70	Brilinta [AP]

▪ **TIOTROPIUM + OLODATEROL**

Note The treatment must not be used in combination with an ICS/LABA, or LAMA or LABA monotherapy.

Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, eformoterol or vilanterol.

Note This product is not PBS-subsidised for the treatment of asthma.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Authority required (STREAMLINED)

5763

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

Patient must have been stabilised on a combination of a long acting muscarinic antagonist and long acting beta-2 agonist.

tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation: solution, 60 actuations

10557P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	91.89	37.70	Spiolto Respimat [BY]

■ TIROFIBAN

Note Shared Care Model:

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

Authority required (STREAMLINED)

5782

High risk of unstable angina

Clinical criteria:

Patient must have new transient or persistent ST-T ischaemic changes, **AND**

Patient must have pain lasting longer than 20 minutes.

Authority required (STREAMLINED)

5809

High risk of unstable angina

Clinical criteria:

Patient must have new transient or persistent ST-T ischaemic changes, **AND**

Patient must have repetitive episodes of angina at rest or during minimal exercise in the previous 12 hours.

Authority required (STREAMLINED)

5691

Non-Q-wave myocardial infarction

tirofiban 12.5 mg/50 mL injection, 1 x 50 mL vial

8350L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	2	..	298.58	37.70	^a Aggrastat [AS]	^a Tirofiban AC [JO]

■ TRIGLYCERIDES LONG CHAIN WITH GLUCOSE POLYMER

Restricted benefit

Proven inborn errors of protein metabolism

Clinical criteria:

Patient must be unable to meet their energy requirements with permitted food and formulae.

triglycerides long chain with glucose polymer oral liquid, 18 x 250 mL cans

9308X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	5	..	*330.51	37.70	ProZero [VF]

triglycerides long chain with glucose polymer oral liquid, 6 x 1000 mL bottles

9309Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*293.49	37.70	ProZero [VF]

■ TRIGLYCERIDES MEDIUM CHAIN

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

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

Authority required

Chylous ascites

Authority required

Chylothorax

Authority required

Fat malabsorption

Clinical criteria:

The condition must be due to liver disease; OR

The condition must be due to short gut syndrome; OR

The condition must be due to cystic fibrosis; OR

The condition must be due to gastrointestinal disorders.

Authority required

Hyperlipoproteinaemia type 1

Authority required

Intractable childhood epilepsy

Clinical criteria:

Patient must require a ketogenic diet.

Cerebrospinal fluid glucose transporter defect

Clinical criteria:

Patient must require a ketogenic diet.

Authority required

Long chain fatty acid oxidation disorders

triglycerides medium chain oil: oral, 500 mL

3128P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*51.89	37.70	MCT Oil [SB]

triglycerides medium chain oral liquid, 1 x 250 mL bottle

9327X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*200.77	37.70	Liquigen [SB]

■ TRIGLYCERIDES MEDIUM CHAIN AND LONG CHAIN WITH GLUCOSE POLYMER**Restricted benefit**

Proven inborn errors of protein metabolism

Clinical criteria:

Patient must be unable to meet their energy requirements with permitted food and formulae.

triglycerides medium chain and long chain with glucose polymer oral liquid: powder for, 400 g

3136C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*284.69	37.70	Duocal [SB]

■ TRIGLYCERIDES MEDIUM CHAIN FORMULA**Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Note** Not indicated for the treatment of intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect requiring a ketogenic diet.**Authority required**

Chylous ascites

Authority required

Chylothorax

Authority required

Fat malabsorption

Clinical criteria:

The condition must be due to liver disease; OR

The condition must be due to short gut syndrome; OR

The condition must be due to cystic fibrosis; OR

The condition must be due to gastrointestinal disorders.

Authority required

Hyperlipoproteinaemia type 1

Authority required

Long chain fatty acid oxidation disorders

triglycerides medium chain formula oral liquid: powder for, 30 x 16 g sachets

9383W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*241.33	37.70	MCT Pro-Cal [VF]

■ TRIPTORELIN**Authority required (STREAMLINED)****5646**

Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate

triptorelin 11.25 mg injection [1 x 11.25 mg vial] (& inert substance diluent [1 x 2 mL ampoule], 1 pack

9379P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1101.16	37.70	Diphereline [IS]

triptorelin 22.5 mg injection [1 x 22.5 mg vial] (& inert substance diluent [1 x 2 mL ampoule], 1 pack

5297T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	2123.34	37.70	Diphereline [IS]

triptorelin 3.75 mg injection [1 x 3.75 mg vial] (& inert substance diluent [1 x 2 mL ampoule], 1 pack

9378N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	413.75	37.70	Diphereline [IS]

■ TROPISETRON**Restricted benefit**

Nausea and vomiting

Clinical criteria:

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

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

tropisetron 5 mg/5 mL injection, 1 x 5 mL ampoule

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

■ UMECLIDINIUM + VILANTEROL

Note The treatment must not be used in combination with an ICS/LABA, or LAMA or LABA monotherapy.

Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, eformoterol or vilanterol.

Note This product is not PBS-subsidised for the treatment of asthma.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Authority required (STREAMLINED)

5763

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

Patient must have been stabilised on a combination of a long acting muscarinic antagonist and long acting beta-2 agonist.

umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation inhalation: powder for, 30 actuations

10188F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	±1	5	..	91.89	37.70	Anoro Ellipta 62.5/25 [GK]	

■ URSODEOXYCHOLIC ACID

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

Note Continuing Therapy Only:

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

Authority required (STREAMLINED)

5757

Primary biliary cirrhosis

ursodeoxycholic acid 250 mg capsule, 100

8448P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*306.81	37.70	^a Ursofalk [OA]	^a Ursosan [BZ]

■ VANCOMYCIN

Restricted benefit

Endocarditis

Clinical criteria:

The treatment must be for prophylaxis, **AND**

Patient must be hypersensitive to penicillin.

vancomycin 1 g injection, 1 x 1 g vial

2269K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	13.52	14.69	^a Hospira Pty Limited [HH] ^a Vancomycin Sandoz [SZ]	^a Vancomycin Alphapharm [AF] ^a Vycin IV [EA]

vancomycin 500 mg injection, 1 x 500 mg vial

3130R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*13.51	14.68	^a Hospira Pty Limited [HH] ^a Vancomycin Alphapharm [AF]	^a Vancocin CP [AS] ^a Vancomycin Sandoz [SZ]

■ VANCOMYCIN

Restricted benefit

Endocarditis

Clinical criteria:

The treatment must be for prophylaxis, **AND**

Patient must be hypersensitive to penicillin.

vancomycin 1 g injection, 1 x 1 g vial

5083M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	13.52	14.69	^a Hospira Pty Limited [HH] ^a Vancomycin Sandoz [SZ]	^a Vancomycin Alphapharm [AF] ^a Vycin IV [EA]

vancomycin 500 mg injection, 1 x 500 mg vial

3323X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	2	..	..	*13.51	14.68	^a Hospira Pty Limited [HH] ^a Vancomycin Alphapharm [AF]	^a Vancocin CP [AS] ^a Vancomycin Sandoz [SZ]

■ VANCOMYCIN**Restricted benefit**

Endophthalmitis

Restricted benefit

Infection

Clinical criteria:The treatment must be initiated in a hospital, **AND**

The condition must be one in which vancomycin is an appropriate antibiotic.

vancomycin 1 g injection, 1 x 1 g vial

2270L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*19.71	20.88	^a Hospira Pty Limited [HH] ^a Vancomycin Sandoz [SZ]	^a Vancomycin Alphapharm [AF] ^a Vycin IV [EA]

vancomycin 500 mg injection, 1 x 500 mg vial

3131T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	..	..	*18.13	19.30	^a Hospira Pty Limited [HH] ^a Vancomycin Alphapharm [AF]	^a Vancocin CP [AS] ^a Vancomycin Sandoz [SZ]

■ VANCOMYCIN

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

Authority required

Antibiotic associated pseudomembranous colitis

Clinical criteria:The condition must be due to Clostridium difficile, **AND**

The condition must be unresponsive to metronidazole.

Authority required

Antibiotic associated pseudomembranous colitis

Clinical criteria:The condition must be due to Clostridium difficile, **AND**

Patient must have an intolerance to metronidazole.

vancomycin 125 mg capsule, 20

3113W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*219.23	37.70	Vancocin [AS]

vancomycin 250 mg capsule, 20

3114X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*434.29	37.70	Vancocin [AS]

■ VENLAFAXINE**Note Continuing Therapy Only:**

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

Restricted benefit

Major depressive disorders

venlafaxine 150 mg capsule: modified release, 28 capsules

8302Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	18.81	19.98	^a Altven [FZ] ^a Blooms the Chemist Venlafaxine XR [IB] ^a Efexor-XR [PF] ^a Enlafax-XR [AF] ^a Venlafaxine Actavis XR [ED] ^a Venlafaxine generichealth XR [GQ] ^a Venlafaxine SR SCP 150 [CR] ^a Venlexor XR [GN]	^a APO-Venlafaxine XR [TX] ^a Chem mart Venlafaxine XR [CH] ^a Elaxine SR 150 [ZP] ^a Terry White Chemists Venlafaxine XR [TW] ^a Venlafaxine AN SR [EA] ^a Venlafaxine Sandoz XR [SZ] ^a Venla RBX [RA]

venlafaxine 37.5 mg capsule: modified release, 28 capsules

8868R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	14.31	15.48	^a Altven [FZ] ^a Elaxine SR 37.5 [ZP] ^a Venlafaxine AN SR [EA]	^a Efexor-XR [PF] ^a Venlafaxine Actavis XR [ED]

venlafaxine 75 mg capsule: modified release, 28 capsules

8301X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.29	18.46	^a Altven [FZ] ^a Blooms the Chemist Venlafaxine XR [IB] ^a Efexor-XR [PF] ^a Enlafax-XR [AF] ^a Venlafaxine Actavis XR [ED] ^a Venlafaxine generichealth XR [GQ] ^a Venlafaxine SR SCP 75 [CR] ^a Venlexor XR [GN]	^a APO-Venlafaxine XR [TX] ^a Chem mart Venlafaxine XR [CH] ^a Elaxine SR 75 [ZP] ^a Terry White Chemists Venlafaxine XR [TW] ^a Venlafaxine AN SR [EA] ^a Venlafaxine Sandoz XR [SZ] ^a Venla RBX [RA]

■ VORICONAZOLE**Note Shared Care Model:**

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

Authority required

Definite or probable invasive aspergillosis

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

Patient must be immunocompromised.

Authority required

Serious fungal infections

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

The condition must be caused by *Scedosporium* species; OR

The condition must be caused by *Fusarium* species.

Authority required

Serious *Candida* infections

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

The condition must be caused by species not susceptible to fluconazole; OR

The condition must be resistant to fluconazole; OR

Patient must be unable to tolerate fluconazole.

Authority required

Serious invasive mycosis infections

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.

voriconazole 200 mg tablet, 56

9364W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	2238.03	37.70	Vfend [PF]

voriconazole 50 mg tablet, 56

9363T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	585.89	37.70	Vfend [PF]

■ VORICONAZOLE

Note Application for an increased maximum quantity to allow for up to 1 month's treatment and repeats sufficient for up to 6 months' treatment may be authorised.

Note Shared Care Model:

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

Authority required

Definite or probable invasive aspergillosis

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

Patient must be immunocompromised.

Authority required

Serious fungal infections

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

The condition must be caused by *Scedosporium* species; OR

The condition must be caused by *Fusarium* species.

Authority required

Serious *Candida* infections

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

The condition must be caused by species not susceptible to fluconazole; OR

The condition must be resistant to fluconazole; OR

Patient must be unable to tolerate fluconazole.

Authority required

Serious invasive mycosis infections

Treatment Phase: Treatment and maintenance therapy

Clinical criteria:

The treatment must be for invasive mycosis infections other than definite or probable invasive aspergillosis.

voriconazole 40 mg/mL oral liquid: powder for, 70 mL

9452L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	#588.54	37.70	Vfend [PF]

■ ZIPRASIDONE**Note Shared Care Model:**

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

Authority required (STREAMLINED)

4246

Schizophrenia

Authority required (STREAMLINED)

5742

Acute mania or mixed episodes

Clinical criteria:

The condition must be associated with bipolar I disorder, **AND**

The treatment must be as monotherapy, **AND**

The treatment must be limited to up to 6 months per episode.

ziprasidone 20 mg capsule, 60

9070J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	64.32	37.70	^a APO-Ziprasidone [TX]	^a Zeldox [PF]

ziprasidone 40 mg capsule, 60

9071K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	118.40	37.70	^a APO-Ziprasidone [TX]	^a Zeldox [PF]

ziprasidone 60 mg capsule, 60

9072L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	171.82	37.70	^a APO-Ziprasidone [TX]	^a Zeldox [PF]

ziprasidone 80 mg capsule, 60

9073M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	227.14	37.70	^a APO-Ziprasidone [TX]	^a Zeldox [PF]

■ ZOLEDRONIC ACID

Note Pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL vial and pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL bag are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

5710

Symptomatic Paget disease of bone

Only 1 treatment each year per patient will be PBS-subsidised

zoledronic acid 5 mg/100 mL injection, 1 x 100 mL vial

9350D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	491.28	37.70	^a Aclasta [NV] ^a Zoledasta [TX]	^a Osteovan [SZ]

zoledronic acid 5 mg/100 mL injection, 100 mL bag

10571J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	491.28	37.70	^a Ostira [HH]

■ ZOLEDRONIC ACID

Note Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.

Note Pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL vial and pharmaceutical benefits that have the form zoledronic acid injection 5 mg/100 mL bag are equivalent for the purposes of substitution.

Authority required (STREAMLINED)**5656**

Corticosteroid-induced osteoporosis

Clinical criteria:

Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy, **AND**

Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less, **AND**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**

Patient must not receive more than one PBS-subsidised treatment per year.

The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)**5765**

Osteoporosis

Clinical criteria:

Patient must have a Bone Mineral Density (BMD) T-score of -3.0 or less, **AND**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**

Patient must not receive more than one PBS-subsidised treatment per year.

Population criteria:

Patient must be aged 70 years or older.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)**5796**

Established osteoporosis

Clinical criteria:

Patient must have fracture due to minimal trauma, **AND**

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition, **AND**

Patient must not receive more than one PBS-subsidised treatment per year.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

zoledronic acid 5 mg/100 mL injection, 1 x 100 mL vial

9288W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	491.28	37.70	^a Aclasta [NV] ^a Zoledasta [TX]	^a Osteovan [SZ]

zoledronic acid 5 mg/100 mL injection, 100 mL bag

10555M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	491.28	37.70	^a Ostira [HH]

Palliative Care

■ BENZYLAMINE

Authority required (STREAMLINED)

5622

Painful mouth

Treatment Phase: Initial treatment

Clinical criteria:

Patient must be receiving palliative care, **AND**

Patient must not receive more than 4 months treatment under this restriction.

benzylamine hydrochloride 0.15% mouthwash, 500 mL

5385K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	\$1	3	..	24.19	25.36	Diffiam [IA]

■ BENZYLAMINE

Note Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

Authority required (STREAMLINED)

5651

Painful mouth

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must be receiving palliative care.

benzylamine hydrochloride 0.15% mouthwash, 500 mL

5386L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	\$1	..	..	24.19	25.36	Diffiam [IA]

■ BISACODYL

Authority required (STREAMLINED)

5774

Constipation

Treatment Phase: Initial treatment, for up to 4 months

Clinical criteria:

Patient must be receiving palliative care.

bisacodyl 10 mg suppository, 10

5303D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	3	..	*23.04	24.21	^a Petrus Bisacodyl Suppositories [PP]
			^B 1.29	*24.33	24.21	^a Dulcolax [BY]

bisacodyl 10 mg suppository, 12

5304E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	3	..	*20.76	21.93	Petrus Bisacodyl Suppositories [PP]

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

5302C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	\$1	3	..	37.83	37.70	Bisalax [AS]

bisacodyl 5 mg tablet: enteric, 200 tablets

5301B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	3	..	17.11	18.28	Lax-Tab [AE]

■ BISACODYL

Note Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

Authority required (STREAMLINED)**5641**

Constipation

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must be receiving palliative care.

bisacodyl 10 mg suppository, 10

5307H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	..	..	*23.04	24.21	^a Petrus Bisacodyl Suppositories [PP]
			^b 1.29	*24.33	24.21	^a Dulcolax [BY]

bisacodyl 10 mg suppository, 12

5308J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	..	..	*20.76	21.93	Petrus Bisacodyl Suppositories [PP]

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

5306G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	..	..	37.83	37.70	Bisalax [AS]

bisacodyl 5 mg tablet: enteric, 200 tablets

5305F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	17.11	18.28	Lax-Tab [AE]

■ GLYCEROL**Authority required (STREAMLINED)****5774**

Constipation

Treatment Phase: Initial treatment, for up to 4 months

Clinical criteria:

Patient must be receiving palliative care.

glycerol 1.4 g suppository, 12

5312N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	3	..	*23.28	24.45	Petrus Pharmaceuticals Pty Ltd [PP]

glycerol 2.8 g suppository, 12

5313P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	3	..	*23.79	24.96	Petrus Pharmaceuticals Pty Ltd [PP]

glycerol 700 mg suppository, 12

5311M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	3	..	*22.89	24.06	Petrus Pharmaceuticals Pty Ltd [PP]

■ GLYCEROL

Note Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

Authority required (STREAMLINED)**5641**

Constipation

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must be receiving palliative care.

glycerol 1.4 g suppository, 12

5315R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	..	..	*23.28	24.45	Petrus Pharmaceuticals Pty Ltd [PP]

glycerol 2.8 g suppository, 12

5316T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	..	..	*23.79	24.96	Petrus Pharmaceuticals Pty Ltd [PP]

glycerol 700 mg suppository, 12

5314Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	..	..	*22.89	24.06	Petrus Pharmaceuticals Pty Ltd [PP]

■ HYOSCINE BUTYLBROMIDE**Authority required (STREAMLINED)****5792**

Colicky pain

Treatment Phase: Initial treatment

Clinical criteria:Patient must be receiving palliative care, **AND**

Patient must not receive more than 4 months treatment under this restriction.

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

5317W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	3	..	*103.23	37.70	Buscopan [BY]

■ HYOSCINE BUTYLBROMIDE

Note Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

Authority required (STREAMLINED)**5673**

Colicky pain

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must be receiving palliative care.

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

5318X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	..	..	*103.23	37.70	Buscopan [BY]

■ METHYLNALTREXONE

Note No applications for repeats will be authorised.

Note Special Pricing Arrangements apply.

Authority required

Opioid-induced constipation

Treatment Phase: Initial treatment

Clinical criteria:The treatment must be in combination with oral laxatives, **AND**Patient must be receiving palliative care, **AND**

Patient must have failed to respond to laxatives.

methylnaltrexone bromide 12 mg/0.6 mL injection, 1 x 0.6 mL vial

5423K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	..	..	*123.30	37.70	Relistor [LM]

■ METHYLNALTREXONE

Note For first continuing supply, applications for increased repeats may be authorised.

Note Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Opioid-induced constipation

Treatment Phase: Continuing treatment

Clinical criteria:The treatment must be in combination with oral laxatives, **AND**

Patient must be receiving palliative care, **AND**
Patient must have demonstrated a response to methylalntrexone.

METHYLNALTREXONE Solution for injection containing methylalntrexone bromide 12 mg in 0.6 mL, 7

5424L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	276.76	37.70	Relistor [LM]

▪ **NITRAZEPAM**

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

Authority required

Insomnia

Treatment Phase: Initial treatment, for up to 4 months

Clinical criteria:

Patient must be receiving palliative care.

nitrazepam 5 mg tablet, 25

5359C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	3	..	*13.65	14.82	^a Alodorm [AF]
			^b 2.48	*16.13	14.82	^a Mogadon [IA]

▪ **NITRAZEPAM**

Note Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.

Authority required

Insomnia

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must be receiving palliative care.

nitrazepam 5 mg tablet, 25

5360D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*13.65	14.82	^a Alodorm [AF]
			^b 2.48	*16.13	14.82	^a Mogadon [IA]

▪ **RHAMNUS FRANGULA + STERCULIA**

Authority required (STREAMLINED)

5774

Constipation

Treatment Phase: Initial treatment, for up to 4 months

Clinical criteria:

Patient must be receiving palliative care.

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

5322D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	3	..	27.77	28.94	Normacol Plus [NE]

▪ **RHAMNUS FRANGULA + STERCULIA**

Note Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

Authority required (STREAMLINED)

5641

Constipation

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must be receiving palliative care.

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

5324F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	..	..	27.77	28.94	Normacol Plus [NE]

▪ **SORBITOL + CITRATE + LAURYL SULFOACETATE SODIUM**

Authority required (STREAMLINED)

5774

Constipation

Treatment Phase: Initial treatment, for up to 4 months

Clinical criteria:

Patient must be receiving palliative care.

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

5331N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*32.91	34.08	^a Micolette [AE]	^a Microlax [JT]

■ SORBITOL + CITRATE + LAURYL SULFOACETATE SODIUM

Note Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.

Authority required (STREAMLINED)

5641

Constipation

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must be receiving palliative care.

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

5332P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*32.91	34.08	^a Micolette [AE]	^a Microlax [JT]

■ TEMAZEPAM

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

Authority required

Insomnia

Treatment Phase: Initial treatment, for up to 4 months

Clinical criteria:

Patient must be receiving palliative care.

temazepam 10 mg tablet, 25

5375X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	3	..	*12.05	13.22	^a APO-Temazepam [TX]	^a Temaze [AF]
						^a Temtabs [FM]	
			^B 6.96	*19.01	13.22	^a Normison [QA]	

■ TEMAZEPAM

Note Where consultation with a palliative care specialist or service has occurred, applications for increased repeats may be authorised.

Authority required

Insomnia

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must be receiving palliative care.

temazepam 10 mg tablet, 25

5376Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	..	..	*12.05	13.22	^a APO-Temazepam [TX]	^a Temaze [AF]
						^a Temtabs [FM]	
			^B 6.96	*19.01	13.22	^a Normison [QA]	

Highly Specialised Drugs Program (Private Hospital)

▪ DORNASE ALFA

Note This drug is not PBS-subsidised for use in combination with PBS-subsidised mannitol.

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

Authority required

Cystic fibrosis

Population criteria:

Patient must be 5 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Authority required

Cystic fibrosis

Clinical criteria:

Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR

Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR

Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR

Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.

Population criteria:

Patient must be less than 5 years of age.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented. Treatment with this drug should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.

Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have initiated treatment with dornase alfa at an age of less than 5 years, **AND**

Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

Population criteria:

Patient must be 5 years of age or older.

Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

dornase alfa 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules

6120D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2406.93	Pulmozyme [RO]

■ EVEROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority required

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**

The treatment must be under the supervision and direction of a transplant unit.

Authority required

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**

The treatment must be under the supervision and direction of a transplant unit.

everolimus 1 mg tablet, 60

9582H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*3891.73	Certican [NV]

everolimus 250 microgram tablet, 60

6459Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*506.75	Certican [NV]

everolimus 500 microgram tablet, 60

6460B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1006.57	Certican [NV]

everolimus 750 microgram tablet, 60

6461C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*2930.53	Certican [NV]

■ MANNITOL

Note This drug is not PBS-subsidised for use in combination with PBS-subsidised dornase alfa.

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

Authority required

Cystic fibrosis

Clinical criteria:

Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result, **AND**

Patient must be intolerant or inadequately responsive to dornase alfa.

Population criteria:

Patient must be 6 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; **AND**

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

MANNITOL Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers, 1

2008Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*1782.93	bronchitol [XA]

■ MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Authority required

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**

The treatment must be under the supervision and direction of a transplant unit.

Authority required

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**

The treatment must be under the supervision and direction of a transplant unit.

mycophenolate mofetil 1 g/5 mL oral liquid: powder for, 165 mL

6364Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*#518.16	CellCept [RO]

mycophenolate mofetil 500 mg tablet, 50

6209T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*452.97	^a APO-Mycophenolate [TX] ^a Ceptolate [AF] ^a Mycophenolate Sandoz [SZ]	^a CellCept [RO] ^a Mycophenolate AN [EA] ^a Pharmacor Mycophenolate 500 [CR]

▪ **MYCOPHENOLATE**

Caution Careful monitoring of patients is mandatory.

Note For item codes 6208R and 1837Q, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution.

Authority required

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**

The treatment must be under the supervision and direction of a transplant unit.

Authority required

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**

The treatment must be under the supervision and direction of a transplant unit.

mycophenolate Capsule 250 mg, 50

1837Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	12	5	..	*453.09	^a Ceptolate [AF]

mycophenolate mofetil 250 mg capsule, 100

6208R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*453.09	^a APO-Mycophenolate [TX] ^a Mycophenolate Sandoz [SZ]	^a CellCept [RO] ^a Pharmacor Mycophenolate 250 [CR]

▪ **OCTREOTIDE**

Note Pharmaceutical benefits that have the form octreotide 10 mg injection (modified release) with 2 mL diluent and pharmaceutical benefits that have the form octreotide 10 mg injection (modified release) with 2.5 mL diluent are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form octreotide 20 mg injection (modified release) with 2 mL diluent and pharmaceutical benefits that have the form octreotide 20 mg injection (modified release) with 2.5 mL diluent are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form octreotide 30 mg injection (modified release) with 2 mL diluent and pharmaceutical benefits that have the form octreotide 30 mg injection (modified release) with 2.5 mL diluent are equivalent for the purposes of substitution.

Authority required

Acromegaly

Clinical criteria:

The condition must be controlled with octreotide immediate release injections, **AND**

The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**

The treatment must cease if IGF1 is not lower after 3 months of treatment.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

Authority required

Functional carcinoid tumour

Clinical criteria:

Patient must have achieved symptom control on octreotide immediate release injections, **AND**

The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

Authority required

Vasoactive intestinal peptide secreting tumour (VIPoma)

Clinical criteria:

Patient must have achieved symptom control on octreotide immediate release injections, **AND**

The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

octreotide 10 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10566D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2660.65	^a Sandostatin LAR [NV]

octreotide 10 mg injection: modified release [1 x 10 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack

6426F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2660.65	^a Sandostatin LAR [NV]

octreotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10549F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*3526.55	^a Sandostatin LAR [NV]

octreotide 20 mg injection: modified release [1 x 20 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack

6427G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*3526.55	^a Sandostatin LAR [NV]

octreotide 30 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10558Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*4401.85	^a Sandostatin LAR [NV]

octreotide 30 mg injection: modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack

6428H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*4401.85	^a Sandostatin LAR [NV]

▪ **SIROLIMUS**

Caution Careful monitoring of patients is mandatory.

Authority required

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**

The treatment must be under the supervision and direction of a transplant unit.

sirolimus 1 mg tablet, 100

6436R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1493.59	Rapamune [PF]

sirolimus 1 mg/mL oral liquid, 60 mL

6437T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*980.37	Rapamune [PF]

sirolimus 2 mg tablet, 100

6457W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2940.27	Rapamune [PF]

sirolimus 500 microgram tablet, 100

9748C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*759.21	Rapamune [PF]

▪ ZOLEDRONIC ACID

Note Pharmaceutical benefits that have the form zoledronic acid 4 mg/100 mL injection and pharmaceutical benefits that have the form zoledronic acid 4 mg/5 mL injection are equivalent for the purposes of substitution.

Authority required

Multiple myeloma

Authority required

Bone metastases

Clinical criteria:

The condition must be due to breast cancer.

Authority required

Bone metastases

Clinical criteria:

The condition must be due to castration-resistant prostate cancer.

Authority required

Hypercalcaemia of malignancy

Clinical criteria:

Patient must have a malignancy refractory to anti-neoplastic therapy.

zoledronic acid 4 mg/100 mL injection, 1 x 100 mL vial

10554L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	346.98	^a Zometa [NV]

zoledronic acid 4 mg/100 mL injection, 100 mL bag

10542W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	346.98	^a DBL Zoledronic Acid [HH]

zoledronic acid 4 mg/5 mL injection, 1 x 5 mL vial

6371H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	346.98	^a APO-Zoledronic Acid [TX] ^a Zometa [NV]	^a DBL Zoledronic Acid [HH]

Highly Specialised Drugs Program (Public Hospital)

▪ DORNASE ALFA

Note This drug is not PBS-subsidised for use in combination with PBS-subsidised mannitol.

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

Authority required (STREAMLINED)

5740

Cystic fibrosis

Population criteria:

Patient must be 5 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Authority required (STREAMLINED)

5634

Cystic fibrosis

Clinical criteria:

Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR

Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR

Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR

Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.

Population criteria:

Patient must be less than 5 years of age.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented. Treatment with this drug should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.

Authority required (STREAMLINED)

5635

Cystic fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have initiated treatment with dornase alfa at an age of less than 5 years, **AND**

Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

Population criteria:

Patient must be 5 years of age or older.

Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

dornase alfa 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules

5704F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2360.00	Pulmozyme [RO]

■ EVEROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)**5795**

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**

The treatment must be under the supervision and direction of a transplant unit.

Authority required (STREAMLINED)**5554**

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**

The treatment must be under the supervision and direction of a transplant unit.

everolimus 1 mg tablet, 60

5737Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*3844.80	Certican [NV]

everolimus 250 microgram tablet, 60

5738B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*480.60	Certican [NV]

everolimus 500 microgram tablet, 60

5739C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*961.20	Certican [NV]

everolimus 750 microgram tablet, 60

5740D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*2883.60	Certican [NV]

■ MANNITOL

Note This drug is not PBS-subsidised for use in combination with PBS-subsidised dornase alfa.

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

Authority required (STREAMLINED)**5799**

Cystic fibrosis

Clinical criteria:

Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result, **AND**

Patient must be intolerant or inadequately responsive to dornase alfa.

Population criteria:

Patient must be 6 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; **AND**

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

MANNITOL Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers, 1

2015C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*1736.00	bronchitol [XA]

■ MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

5795

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**

The treatment must be under the supervision and direction of a transplant unit.

Authority required (STREAMLINED)

5554

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**

The treatment must be under the supervision and direction of a transplant unit.

mycophenolate mofetil 1 g/5 mL oral liquid: powder for, 165 mL

9500B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*489.02	CellCept [RO]

mycophenolate mofetil 500 mg tablet, 50

9502D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*428.88	^a APO-Mycophenolate [TX] ^a Ceptolate [AF] ^a Mycophenolate Sandoz [SZ]	^a CellCept [RO] ^a Mycophenolate AN [EA] ^a Pharmacor Mycophenolate 500 [CR]

■ MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Note For item codes 9501C and 1839T, pharmaceutical benefits that have the form capsule 250 mg are equivalent for the purposes of substitution

Authority required (STREAMLINED)

5653

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**

The treatment must be under the supervision and direction of a transplant unit.

Authority required (STREAMLINED)

5600

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**

The treatment must be under the supervision and direction of a transplant unit.

mycophenolate Capsule 250 mg, 50

1839T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	12	5	..	*429.00	^a Ceptolate [AF]

mycophenolate mofetil 250 mg capsule, 100

9501C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*429.00	^a APO-Mycophenolate [TX] ^a Mycophenolate Sandoz [SZ]	^a CellCept [RO] ^a Pharmacor Mycophenolate 250 [CR]

■ OCTREOTIDE

Note Pharmaceutical benefits that have the form octreotide 10 mg injection (modified release) with 2 mL diluent and pharmaceutical benefits that have the form octreotide 10 mg injection (modified release) with 2.5 mL diluent are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form octreotide 20 mg injection (modified release) with 2 mL diluent and pharmaceutical benefits that have the form octreotide 20 mg injection (modified release) with 2.5 mL diluent are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form octreotide 30 mg injection (modified release) with 2 mL diluent and pharmaceutical benefits that have the form octreotide 30 mg injection (modified release) with 2.5 mL diluent are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

5737

Acromegaly

Clinical criteria:

The condition must be controlled with octreotide immediate release injections, **AND**

The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**

The treatment must cease if IGF1 is not lower after 3 months of treatment.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

Authority required (STREAMLINED)

5738

Functional carcinoid tumour

Clinical criteria:

Patient must have achieved symptom control on octreotide immediate release injections, **AND**

The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

Authority required (STREAMLINED)

5678

Vasoactive intestinal peptide secreting tumour (VIPoma)

Clinical criteria:

Patient must have achieved symptom control on octreotide immediate release injections, **AND**

The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

octreotide 10 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10543X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2613.72	^a Sandostatin LAR [NV]

octreotide 10 mg injection: modified release [1 x 10 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack

9511N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2613.72	^a Sandostatin LAR [NV]

octreotide 20 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10533J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*3479.62	^a Sandostatin LAR [NV]

octreotide 20 mg injection: modified release [1 x 20 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack

9512P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*3479.62	^a Sandostatin LAR [NV]

octreotide 30 mg injection: modified release [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10550G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*4354.92	^a Sandostatin LAR [NV]

octreotide 30 mg injection: modified release [1 x 30 mg vial] (&) inert substance diluent [1 x 2.5 mL syringe], 1 pack

9513Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*4354.92	^a Sandostatin LAR [NV]

■ **SIROLIMUS**

Caution Careful monitoring of patients is mandatory.

Authority required (STREAMLINED)

5795

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**

The treatment must be under the supervision and direction of a transplant unit.

sirolimus 1 mg tablet, 100

9549N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1446.66	Rapamune [PF]

sirolimus 1 mg/mL oral liquid, 60 mL

9550P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*936.00	Rapamune [PF]

sirolimus 2 mg tablet, 100

9548M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2893.34	Rapamune [PF]

sirolimus 500 microgram tablet, 100

9747B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*723.34	Rapamune [PF]

■ ZOLEDRONIC ACID

Note Pharmaceutical benefits that have the form zoledronic acid 4 mg/100 mL injection and pharmaceutical benefits that have the form zoledronic acid 4 mg/5 mL injection are equivalent for the purposes of substitution.

Authority required (STREAMLINED)**5735**

Multiple myeloma

Authority required (STREAMLINED)**5605**

Bone metastases

Clinical criteria:

The condition must be due to breast cancer.

Authority required (STREAMLINED)**5703**

Bone metastases

Clinical criteria:

The condition must be due to castration-resistant prostate cancer.

Authority required (STREAMLINED)**5704**

Hypercalcaemia of malignancy

Clinical criteria:

Patient must have a malignancy refractory to anti-neoplastic therapy.

zoledronic acid 4 mg/100 mL injection, 1 x 100 mL vial

10548E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	326.97	^a Zometa [NV]

zoledronic acid 4 mg/100 mL injection, 100 mL bag

10561W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	326.97	^a DBL Zoledronic Acid [HH]

zoledronic acid 4 mg/5 mL injection, 1 x 5 mL vial

9653C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	326.97	^a APO-Zoledronic Acid [TX] ^a Zometa [NV]	^a DBL Zoledronic Acid [HH]

Highly Specialised Drugs Program (Community Access)

▪ TIPRANAVIR

Authority required (STREAMLINED)

5764

HIV infection

Clinical criteria:

The treatment must be in addition to optimised background therapy, **AND**

The treatment must be in combination with other antiretroviral agents, **AND**

Patient must be antiretroviral experienced, **AND**

The treatment must be co-administered with 200 mg ritonavir twice daily, **AND**

Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

tipranavir 250 mg capsule, 120

10344K

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2	5	..	*1760.53	37.70	Aptivus [BY]

Growth Hormone Program

▪ SOMATROPIN

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Short stature and slow growth

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height below the 1st percentile for age and sex, **AND**

Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**

Patient must not have a bone age of 2.5 years or less, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, **AND**

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**

Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; OR

Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation of the patient's maturational or constitutional delay status; AND
6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1st adult height percentile; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height below the 1st percentile for age and sex, **AND**

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**

Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**

Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Initial treatment

Clinical criteria:

Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR

Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR

Patient must be female and menarche occurred before the chronological age of 10 years, **AND**

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Confirmation that the patient has precocious puberty; AND
7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a structural lesion that is not neoplastic; OR

Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, **AND**

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels, **AND**

Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**

Patient must have hypothalamic obesity, **AND**

Patient must be male, have a chronological age of at least 12 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity above the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity above the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of greater than 8 cm per year, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR

(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

8. Confirmation that the patient has hypothalamic obesity; AND

9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height at or below the 95th percentile for age on the Turner syndrome growth curve for girls, **AND**

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**

Patient must not have a bone age of 2.5 years or less, **AND**

Patient must not have a height greater than or equal to 155.0 cm, **AND**

Patient must not have a bone age of 13.5 years or greater.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height below the 1st percentile for age and sex, **AND**

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**

Patient must be male, have a chronological age of at least 12 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity below the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity below the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

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4. A bone age result performed within the last 12 months; AND
 5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
 6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
 7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a current height at or below the 25th percentile for age and sex, **AND**

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**

Patient must be male, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a chronological age of at least 12 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be male, have a bone age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a chronological age of at least 10 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must be female, have a bone age of at least 8 years and a growth velocity equal to or less than the 25th percentile for bone age and sex measured over a 6 month interval; OR

Patient must have a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both 12 and 6 month intervals; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less; OR

Patient must have a bone age of 2.5 years or less and an annual growth velocity of 8 cm per year or less, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR

(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; AND

6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

10518N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	223.15	37.70	Omnitrope Surepal 5 [SZ]

somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

10514J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	439.36	37.70	Omnitrope Surepal 10 [SZ]

■ **SOMATROPIN**

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Short stature and slow growth

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**

Patient must not have been on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, **AND**

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

Population criteria:

Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**

4. A bone age result performed within the last 12 months; **AND**

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must not have a chronological age of 5 years or greater.

Population criteria:

Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**

4. A bone age result performed within the last 12 months; **AND**

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**

4. A bone age result performed within the last 12 months; **AND**

5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**

Patient must not have been on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must not have a bone age of 13.5 years or greater, **AND**

Patient must not have a height greater than or equal to 155.0 cm.

Population criteria:

Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**

4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).
Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**

Patient must not have been on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**

Patient must not have been on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**

Patient must not have an eGFR equal to or greater than 30mL/min/1.73m2, **AND**

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m2 prescribers should seek reclassification to the indication short stature and slow growth.

Authority required

Short stature and slow growth

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, **AND**

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months;

OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; **AND**

4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**

6. A bone age result performed within the last 12 months; **AND**

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); OR

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); **AND**

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**

6. A bone age result performed within the last 12 months; **AND**

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a paediatric endocrinologist; OR

Must be treated by a medical practitioner in consultation with an endocrinologist specialising in paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

(b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

(c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR

Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR

Patient must be female and menarche occurred before the chronological age of 10 years, **AND**

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. Confirmation that the patient has precocious puberty; **AND**
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
7. A bone age result performed within the last 12 months; **AND**

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must have a structural lesion that is not neoplastic; OR

Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, **AND**

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**

Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**

Patient must have hypothalamic obesity, **AND**

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; **AND**
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; **AND**
7. Confirmation that the patient has hypothalamic obesity; **AND**
8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
9. A bone age result performed within the last 12 months; **AND**
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must not have a bone age of 2.5 years or less, **AND**

Patient must not have a bone age of 13.5 years or greater, **AND**

Patient must not have a height greater than or equal to 155.0 cm.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. A height measurement from immediately prior to commencement of growth hormone treatment; **AND**

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4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
 5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
 6. A bone age result performed within the last 12 months; AND
 7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR

(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; **AND**

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; **AND**

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**

7. A bone age result performed within the last 12 months; **AND**

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, **AND**

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone;
OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone;
OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant;
OR

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
 3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
 4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m² ; AND
 5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
 6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
 7. A bone age result performed within the last 12 months; AND
- The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).
- Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.
- Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m² prescribers should seek reclassification to the indication short stature and slow growth.

somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

10507B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	223.15	37.70	Omnitrope Surepal 5 [SZ]

somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

10506Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	439.36	37.70	Omnitrope Surepal 10 [SZ]

■ SOMATROPIN

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

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

Applications for authority to prescribe should be forwarded to:
 Department of Human Services
 Prior Written Approval of Complex Drugs
 Reply Paid 9826
 HOBART TAS 7001

Authority required

Short stature and slow growth

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**

Patient must have had a lapse in growth hormone treatment, **AND**

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, **AND**

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**

Patient must have had a lapse in growth hormone treatment, **AND**

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**

Patient must have had a lapse in growth hormone treatment, **AND**

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program)

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**

Patient must have had a lapse in growth hormone treatment, **AND**

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must not have a chronological age of 5 years or greater.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**

Patient must have had a lapse in growth hormone treatment, **AND**

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**

Patient must have had a lapse in growth hormone treatment, **AND**

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program)

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**

Patient must have had a lapse in growth hormone treatment, **AND**

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be female and must not have a bone age of 13.5 years or more, **AND**

Patient must be female and must not have a height greater than or equal to 155.0cm.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**

Patient must have had a lapse in growth hormone treatment, **AND**

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, **AND**

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**

Patient must have had a lapse in growth hormone treatment, **AND**

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**

Patient must not have an eGFR equal to or greater than 30mL/min/1.73m2, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more, **AND**

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program)

Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND

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4. A bone age result performed within the last 12 months; AND
 5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m²; AND
 6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
 7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

If a patient receiving treatment under the indication 'short stature associated with chronic renal insufficiency' undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m² prescribers should seek reclassification to the indication short stature and slow growth.

Note If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for recommencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature and slow growth

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and slow growth, **AND**

Patient must have had a lapse in growth hormone treatment, **AND**

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to

commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a height greater than or equal to 167.7 cm; OR

Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment; AND
4. A bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with biochemical growth hormone deficiency, **AND**

Patient must have had a lapse in growth hormone treatment, **AND**

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone;
OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone;
OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must have previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and have reached or surpassed 5 years of age (chronological); OR

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**

Patient must have had a lapse in growth hormone treatment, **AND**

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must have had an intracranial lesion and have undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR

Patient must have had an intracranial lesion, have received medical advice that it is unsafe to treat the intracranial lesion, and have undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR

Patient must have received cranial irradiation without having had an intracranial lesion, and have undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received, **AND**

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8cm per year or less in the 12 month period immediately prior to commencement of growth hormone treatment, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each commencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for commencement of treatment as a reclassified patient; **AND**

3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
- (b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for the intracranial lesion (all treatment); OR
- (b) Confirmation that the patient has had an intracranial lesion, has received medical advice that it is unsafe to treat the intracranial lesion, and has undergone a 12 month period of observation since initial diagnosis of the intracranial lesion; OR
- (c) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion, and has undergone a 12 month period of observation following completion of treatment for the condition for which cranial irradiation was received; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).
- Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**

Patient must have had a lapse in growth hormone treatment, **AND**

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR

Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR

Patient must be female and menarche occurred before the chronological age of 10 years, **AND**

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**

Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. Confirmation that the patient has precocious puberty; **AND**
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. Recent growth data (height and weight, not older than three months); **AND**
7. A bone age result performed within the last 12 months; **AND**
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**

Patient must have had a lapse in growth hormone treatment, **AND**

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must have a structural lesion that is not neoplastic; OR

Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, **AND**

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10mU/L in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**

Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**

Patient must have hypothalamic obesity, **AND**

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment and a growth velocity above the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a growth velocity above the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less at commencement of growth hormone treatment and an annual growth velocity of 8 cm per year or greater in the twelve month period immediately prior to commencement of growth hormone treatment, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
7. Confirmation that the patient has hypothalamic obesity; AND
8. Recent growth data (height and weight, not older than three months); AND
9. A bone age result performed within the last 12 months; AND
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**

Patient must have had a lapse in growth hormone treatment, **AND**

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone;
OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone;
OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must have had a height at or below the 95th percentile for age on the Turner syndrome growth curve for girls immediately prior to commencing growth hormone treatment, **AND**

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR

Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must not have a bone age of 2.5 years or less, **AND**

Patient must not have a height greater than or equal to 155.0 cm, **AND**

Patient must not have a bone age of 13.5 years or greater.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. A height measurement from immediately prior to commencement of growth hormone treatment; **AND**
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; **AND**
5. Recent growth data (height and weight, not older than three months); **AND**
6. A bone age result performed within the last 12 months; **AND**

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**

Patient must have had a lapse in growth hormone treatment, **AND**

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity below the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8 cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height below the 1st percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with chronic renal insufficiency, **AND**

Patient must have had a lapse in growth hormone treatment, **AND**

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must be male, had a chronological age of at least 12 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be male, had a bone age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a chronological age of at least 10 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must be female, had a bone age of at least 8 years at commencement of growth hormone treatment, a growth velocity equal to or less than the 25th percentile for bone age and sex measured over the 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a growth velocity equal to or less than the 25th percentile for bone age and sex measured over both the 12 month and 6 month interval immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment; OR

Patient must have had a bone age of 2.5 years or less immediately prior to commencement of growth hormone treatment, an annual growth velocity of 8cm per year or less in the twelve month period immediately prior to commencement of growth hormone treatment, and a height equal to or less than the 25th percentile for age and sex immediately prior to commencing growth hormone treatment, **AND**

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR

Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**

Patient must not have diabetes mellitus, **AND**

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

Patient must be male and must not have a height greater than or equal to 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

Population criteria:

Patient must be aged 3 years or older.

Treatment criteria:

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, at intervals no greater than six months, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; OR
(b) If the patient was an older child (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over) at the time of commencement of growth hormone treatment, a minimum of 6 months of growth data (height and weight) from immediately prior to commencement of growth hormone treatment, and a bone age result performed within the 12 months immediately prior to commencement of growth hormone treatment; **AND**
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m² ; **AND**
5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; **AND**
6. Recent growth data (height and weight, not older than three months); **AND**
7. A bone age result performed within the last 12 months; **AND**
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Note If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m² prescribers should seek reclassification to the indication short stature and slow growth.

somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

10512G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	223.15	37.70	Omnitrope Surepal 5 [SZ]

somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

10519P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	439.36	37.70	Omnitrope Surepal 10 [SZ]

Repatriation Pharmaceutical Benefits Scheme

■ ASPIRIN

Note The enteric coated preparations are for patients with a significant risk of gastrointestinal bleeding.

aspirin 100 mg capsule: enteric, 84

4078P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	17.55	6.10	Astrix [YN]

aspirin 100 mg tablet: enteric, 84

4077N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	16.76	6.10	^a Cartia [AS]	^a Pharmacy Action Low Dose Aspirin [GQ]

■ AZITHROMYCIN

Restricted benefit

Upper and lower respiratory tract infections

azithromycin 500 mg tablet, 3

4115N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	32.24	6.10	Zedd 500 [QA] ^a APO-Azithromycin [TX] ^a Azithromycin Sandoz [SZ] ^a Terry White Chemists Azithromycin [TW] ^a Zitrocin [GN]	^a Azithromycin-GA [UA] ^a Chem mart Azithromycin [CH] ^a Zithromax [PF]

■ BANDAGE COMPRESSION

Note Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma & Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS pricing from distributors other than those aforementioned.

bandage compression bandage: four layer, 1 bandage

4598B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*149.73	6.10	Profore Lite 66050415 [SN]

bandage compression bandage: four layer, 1 bandage

4658E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*221.08	6.10	Profore 66050016 [SN]

■ BANDAGE COMPRESSION

Note Treatment of varices and oedema associated with venous disease and lymphoedema; contraindicated in arterial disease.

Note Bandage can be left in situ for up to 7 days as per manufacturer's instructions.

Restricted benefit

Venous ulcer

Treatment Phase: Initial treatment

Restricted benefit

Venous ulcer

Treatment Phase: Continuing treatment

bandage compression bandage: two layer, 1 bandage

4050E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	42.18	6.10	Coban 2 [MM]

■ BANDAGE ZINC PASTE

Note Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

bandage zinc paste 10 cm x 9.1 m bandage, 1

4670T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*29.87	6.10	Flexidress 650941 [CC]

■ BANDAGE ZINC PASTE

Note Used as an adjunct in the management of leg ulceration and associated eczema and skin conditions.

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bandage zinc paste 7.5 cm x 6 m bandage, 1

4750B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*79.43	6.10	Viscopaste 4948 [SN]

bandage zinc paste 80 cm (stockings) bandage, 4

4760M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	3	..	91.02	6.10	ZipZoc 66000747 [SN]

■ BROMAZEPAM

Note This drug should not be used as the first line of treatment.

Note Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate.

Note Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

Authority required

Terminal disease

Clinical criteria:

The treatment must be for the short-term, **AND**

Patient must be receiving palliative care.

Authority required

Refractory phobic or anxiety states

Clinical criteria:

The treatment must be for the short-term, **AND**

Patient must be receiving palliative care.

bromazepam 3 mg tablet, 30

4150K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*30.49	6.10	Lexotan [RO]

bromazepam 6 mg tablet, 30

4151L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*36.23	6.10	Lexotan [RO]

■ BUSPIRONE**Authority required**

Anxiety

Clinical criteria:

The treatment must be for the short-term.

buspirone hydrochloride 10 mg tablet, 50

4145E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	54.34	6.10	Buspar [QA]

buspirone hydrochloride 5 mg tablet, 50

4144D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	37.87	6.10	Buspar [QA]

■ CADEXOMER-IODINE

Note Suitable for yellow sloughy infected and malodorous wounds.

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DRESSING with CADEXOMER IODINE Sheets 17 g (10 cm x 8 cm), 2, 1

4937W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	153.29	6.10	Iodosorb 66051360 [SN]

DRESSING with CADEXOMER IODINE Sheets 5 g (6 cm x 4 cm), 5, 1

4935R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	102.08	6.10	Iodosorb 66051330 [SN]

cadexomer-iodine 3 g powder: dusting sterile, 7 x 3 g sachets

4931M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	68.50	6.10	Iodosorb Powder 66051070 [SN]

cadexomer-iodine 50% (500 mg/g) ointment, 2 x 20 g tubes

4933P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	106.79	6.10	Iodosorb Ointment 66051230 [SN]

cadexomer-iodine 50% (500 mg/g) ointment, 4 x 10 g tubes

4932N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	107.76	6.10	Iodosorb Ointment 66051240 [SN]

cadexomer-iodine 8 cm x 6 cm dressing, 3 x 10 g sheets

4936T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	145.67	6.10	Iodosorb 66051340 [SN]

■ CALCIUM CARBONATE + GLYCINE

Note For patients with chronic renal failure.

calcium carbonate 420 mg + glycine 180 mg tablet: chewable, 100

4055K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*25.01	6.10	Titralac [MM]

■ DRESSING ALGINATE CAVITY WOUND

Note This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 1

4832H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	..	..	*103.83	6.10	Sorbsan 1411 [UM]

DRESSING-ALGINATE (CAVITY WOUND) Rope 2 g, 5

1905G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*109.37	6.10	Kaltostat 168117 [CC]

■ DRESSING ALGINATE CAVITY WOUND

Note This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

Note Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

dressing alginate cavity wound 2 g (40 cm) rope, 6 x 2 g

4682K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*129.79	6.10	Comfeel SeaSorb Filler 3740 [CT]

■ DRESSING ALGINATE SUPERFICIAL WOUND

Note This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

dressing alginate superficial wound 7.5 cm x 12 cm dressing, 10

4683L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	87.38	6.10	Kaltostat 168212 [CC]

■ DRESSING ALGINATE SUPERFICIAL WOUND

Note This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

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dressing alginate superficial wound 10 cm x 10 cm dressing, 10

4700J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	104.59	6.10	Algisite M 66000520 [SN]

dressing alginate superficial wound 15 cm x 20 cm dressing, 10

4691X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	250.74	6.10	Algisite M 66000521 [SN]

dressing alginate superficial wound 5 cm x 5 cm dressing, 10

4699H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	48.90	6.10	Kaltostat 168210 [CC]
			..	55.86	6.10	Algisite M 66000519 [SN]

■ DRESSING ALGINATE SUPERFICIAL WOUND

Note This dressing should be used only on moderately to heavily exuding wounds and should remain in place until saturated or for a maximum of 3 days.

Note Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

dressing alginate superficial wound 10 cm x 10 cm dressing, 1

4831G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	1	..	*81.33	6.10	Sorbsan 1410 [UM]
			..	*86.53	6.10	Comfeel SeaSorb Dressing 3710 [CT]

dressing alginate superficial wound 5 cm x 5 cm dressing, 1

4684M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	1	..	*46.43	6.10	Comfeel SeaSorb Dressing 3705 [CT]

■ DRESSING FILM

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

dressing film 10 cm x 12 cm dressing, 10

4893M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	34.18	6.10	Op-Site Flexigrid 4629 [SN]

■ DRESSING FILM ISLAND

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

dressing film island 5 cm x 7.2 cm dressing, 5

4898T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*30.05	6.10	Cutifilm Plus 36361370 [SN]

dressings film island 8 cm x 10 cm dressing, 5

4899W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*45.09	6.10	Cutifilm Plus 36361371 [SN]

▪ DRESSING FOAM HEAVY EXUDATE

Note This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

dressings foam heavy exudate 10 cm x 10 cm dressing, 10

4795J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	125.00	6.10	Allevyn 66007637 [SN]

▪ DRESSING FOAM MODERATE EXUDATE

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dressings foam moderate exudate cavity conforming foam, 1 x 20 g sachet

4694C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	94.67	6.10	Cavicare 4563 [SN]

▪ DRESSING FOAM MODERATE EXUDATE

Note This dressing should remain in place until saturated or up to a maximum of 7 days. Allow a minimum of 2 cm to 3 cm in excess of the wound size of the dressing around the wound.

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

dressings foam moderate exudate 12.5 cm x 12.5 cm dressing, 10

4590N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	129.97	6.10	Allevyn Adhesive 66000044 [SN]

▪ DRESSING FOAM WITH SILICONE AND SILVER

Note Molnlycke Health Care products are distributed through leading pharmacy distributors. To best ensure product availability at the RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email: customerservice@independenceaustralia.com. Molnlycke Health Care is not able to ensure product availability or pricing on listed products beyond these two suppliers.

Authority required

Wounds

Clinical criteria:

Patient must have a wound where there is evidence of critical colonisation; OR

Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

dressings foam with silicone and silver 10 cm x 10 cm dressing, 5

2439J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	103.95	6.10	Mepilex Ag [MH]

dressings foam with silicone and silver 10 cm x 10 cm dressing, 5

2470B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	111.00	6.10	Mepilex Border Ag [MH]

▪ DRESSING FOAM WITH SILICONE HEAVY EXUDATE

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

dressings foam with silicone heavy exudate 10 cm x 10 cm dressing, 10

4196W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	74.07	6.10	Allevyn Gentle 66800248 [SN]

dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 10

4230P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	74.07	6.10	Allevyn Gentle Border 66800270 [SN]

dressing foam with silicone heavy exudate 7.5 cm x 7.5 cm dressing, 10

4207K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	52.86	6.10	Allevyn Gentle Border 66800269 [SN]

▪ DRESSING FOAM WITH SILICONE HEAVY EXUDATE

Note Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

dressing foam with silicone heavy exudate 10 cm x 10 cm dressing, 5

4643J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	42.18	6.10	Mepilex Border 295300 [MH]

dressing foam with silicone heavy exudate 7.5 cm x 7.5 cm dressing, 5

4642H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	31.59	6.10	Mepilex Border 295200 [MH]

▪ DRESSING FOAM WITH SILICONE LIGHT EXUDATE

Note Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

dressing foam with silicone light exudate 10 cm x 10 cm dressing, 5

4645L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	38.06	6.10	Mepilex Lite 284100 [MH]

dressing foam with silicone light exudate 6 cm x 8.5 cm dressing, 5

4644K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	29.24	6.10	Mepilex Lite 284000 [MH]

▪ DRESSING FOAM WITH SILICONE MODERATE EXUDATE

Note Molnlycke Healthcare products are distributed through leading pharmacy distributors. To best ensure product availability at RPBS agreed prices, special arrangements have been made with API and Independence Australia Health Solutions (IAHS). IAHS orders can be placed on: Tel: 1300 788 855; or Email customerservice@independenceaustralia.com. Molnlycke Healthcare are not able to ensure product availability or pricing on listed products beyond these two suppliers.

dressing foam with silicone moderate exudate 10 cm x 10 cm dressing, 5

4626L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	42.18	6.10	Mepilex 294100 [MH]

▪ DRESSING FOAM WITH SILVER

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

Authority required

Wounds

Clinical criteria:

Patient must have a wound where there is evidence of critical colonisation; OR

Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

dressing foam with silver 10 cm x 10 cm dressing, 10

4255Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	196.81	6.10	Allevyn Ag Adhesive 66800075 [SN]

dressings foam with silver 10 cm x 10 cm dressing, 10

4259E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	200.63	6.10	Allevyn Ag Non-Adhesive 66800086 [SN]

dressings foam with silver 10 cm x 10 cm dressing, 10

4266M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	196.81	6.10	Allevyn Ag Gentle Border 66800461 [SN]

dressings foam with silver 12.5 cm x 12.5 cm dressing, 10

4258D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	244.97	6.10	Allevyn Ag Adhesive 66800078 [SN]

dressings foam with silver 12.5 cm x 12.5 cm dressing, 10

4270R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	244.97	6.10	Allevyn Ag Gentle Border 66800462 [SN]

dressings foam with silver 7.5 cm x 7.5 cm dressing, 10

4252T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	133.61	6.10	Allevyn Ag Adhesive 66800073 [SN]

dressings foam with silver 7.5 cm x 7.5 cm dressing, 10

4263J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	133.61	6.10	Allevyn Ag Gentle Border 66800460 [SN]

▪ DRESSING GAUZE PARAFFIN

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dressings gauze paraffin 10 cm x 10 cm dressing, 10

4759L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	23.64	6.10	Jelonet 7404 [SN]

▪ DRESSING GAUZE PARAFFIN WITH CHLORHEXIDINE ACETATE

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

dressings gauze paraffin with chlorhexidine acetate 10 cm x 10 cm dressing, 10

4845B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	25.98	6.10	Bactigras 7457 [SN]

▪ DRESSING HYDROACTIVE CAVITY WOUND

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

dressings hydroactive cavity wound 10 cm x 10 cm dressing, 5

4919X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*195.35	6.10	Allevyn Plus Cavity 66047573 [SN]

dressings hydroactive cavity wound 5 cm x 6 cm dressing, 10

4918W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	94.43	6.10	Allevyn Plus Cavity 66047571 [SN]

▪ DRESSING HYDROACTIVE DEBRIDEMENT

Note Hartmann wound dressings are available through HARTMANN and Independence Australia only. If you would like to order Hartmann Wound Care products, please call HARTMANN customer service on 1800 805 839 or Independence Australia on 1300 788 855.

DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 4 cm, 10, 1

4949L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	81.75	6.10	TenderWet 24 Active 609210 [HR]

DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 5.5 cm, 10, 1

4948K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	83.61	6.10	TenderWet Active Cavity 609272 [HR]

DRESSING-HYDROACTIVE (DEBRIDEMENT) Dressings 7.5 cm x 7.5 cm, 10, 1

4950M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	109.35	6.10	TenderWet 24 Active 609213 [HR]

▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND HIGH EXUDATE SEMI-PERMEABLE ABSORBENT FOAM

Note Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

dressings hydroactive superficial wound high exudate semi-permeable absorbent foam 10 cm x 10 cm pad: waterproof, 10 pads

4927H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	84.52	6.10	Biatain Non-adhesive 3410 [CT]

dressings hydroactive superficial wound high exudate semi-permeable absorbent foam 12 cm x 12 cm pad: waterproof, 10 pads

4929K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	92.72	6.10	Biatain Adhesive 3420 [CT]

dressings hydroactive superficial wound high exudate semi-permeable absorbent foam 15 cm x 15 cm pad: waterproof, 5 pads

4928J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	83.17	6.10	Biatain Non-adhesive 3413 [CT]

dressings hydroactive superficial wound high exudate semi-permeable absorbent foam 18 cm x 18 cm pad: waterproof, 5 pads

4930L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	2	..	89.87	6.10	Biatain Adhesive 3423 [CT]

▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND LIGHT EXUDATE

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

dressings hydroactive superficial wound light exudate 10 cm x 10 cm dressing, 5

4906F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*107.55	6.10	Allevyn Thin 66047578 [SN]

dressings hydroactive superficial wound light exudate 5 cm x 6 cm dressing, 10

4905E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	1	..	60.70	6.10	Allevyn Thin 66047576 [SN]

▪ DRESSING HYDROACTIVE SUPERFICIAL WOUND MODERATE EXUDATE

Note Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

4886E dressing hydroactive superficial wound moderate exudate 10 cm x 10 cm dressing, 5

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2	1	..	*85.15	6.10	Cutinova Hydro 66047443 [SN]

4885D dressing hydroactive superficial wound moderate exudate 5 cm x 6 cm dressing, 10

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	1	..	52.04	6.10	Cutinova Hydro 66047441 [SN]

■ DRESSING HYDROFIBRE WITH SILVER**Authority required**

Wounds

Clinical criteria:

Patient must have a wound where there is evidence of critical colonisation; OR

Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

10097K dressing hydrofibre with silver 10 cm x 10 cm dressing, 10

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	1	..	250.08	6.10	Aquacel Ag 403708 [CC]

10098L dressing hydrofibre with silver 15 cm x 15 cm dressing, 5

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	1	..	267.72	6.10	Aquacel Ag 403710 [CC]

10105W dressing hydrofibre with silver 2 cm x 45 cm rope, 5

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	1	..	211.14	6.10	Aquacel Ag 403771 [CC]

■ DRESSING WITH SILVER

Note Coloplast dressings are available via a range of distributors. However, Coloplast's principal agreement to ensure correct RPBS Price to Pharmacy and ready supply has been secured with Independence Australia on 1300 788 855 and BrightSky on 1300 290 400. Please note that Coloplast is unable to guarantee ready supply or rebate for price differences on purchases outside these distributors.

Authority required

Wounds

Clinical criteria:

Patient must have a wound where there is evidence of critical colonisation; OR

Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

4646M dressing with silver 10 cm x 10 cm dressing: hydroactive, 5 dressings

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	..	..	164.47	6.10	Biatain Ag 9622 [CT]

4647N dressing with silver 12.5 cm x 12.5 cm dressing: hydroactive, 5 dressings

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	..	..	178.48	6.10	Biatain Ag 9632 [CT]

■ DRESSING WITH SILVER

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Authority required

Wounds

Clinical criteria:

Patient must have a wound where there is evidence of critical colonisation; OR

Patient must have a well-assessed chronic wound that has not responded to conventional dressings.

4648P dressing with silver 10 cm x 10 cm dressing: tulle, 3 dressings

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	..	..	43.28	6.10	Atrauman Ag 499572 [HR]

■ FLUNITRAZEPAM

Note This drug should not be used as the first line of treatment.

Note Other PBS-listed benzodiazepines should have been adequately tried and found to be ineffective or inappropriate.

Note Authorities for increased quantities and/or repeats may be granted to patients with terminal disease, and other patients who have been shown to be dependent on this item by an unsuccessful attempt at gradual withdrawal.

Authority required

Terminal disease

Clinical criteria:

The treatment must be for the short-term, **AND**
 Patient must be receiving palliative care.

Authority required

Refractory phobic or anxiety states

Clinical criteria:

The treatment must be for the short-term, **AND**
 Patient must be receiving palliative care.

flunitrazepam 1 mg tablet, 30

4216X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	18.33	6.10	Hypnodorm [AF]

■ GLYCEROL**Restricted benefit**

Constipation

Clinical criteria:

The treatment must be for the short-term, **AND**
 Patient must be one in whom oral laxative therapy has failed; OR
 Patient must be one in whom oral laxative therapy is inappropriate.

glycerol 2.8 g suppository, 12

4246L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*23.79	6.10	Petrus Pharmaceuticals Pty Ltd [PP]

■ ICHTHAMMOL**Note** For patients who have failed to respond to simple moisturising agents.**ichthammol Cream 5 mg-10 mg-10 mg per g (0.5%-1%-1%), 50 g, 1**

4281H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	20.58	6.10	Egoderm Cream [EO]

■ ICHTHAMMOL + ZINC OXIDE**Note** For patients who have failed to respond to simple moisturising agents.**ichthammol 1% (10 mg/g) + zinc oxide 15% (150 mg/g) ointment, 50 g**

4280G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	20.58	6.10	Egoderm Ointment [EO]

■ MOMETASONE**Note** Application to large areas of skin for longer than four weeks is not recommended.**mometasone furoate 0.1% (1 mg/g) cream, 50 g**

4342M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	33.95	6.10	Elocon [MK]

mometasone furoate 0.1% (1 mg/g) ointment, 50 g

4343N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	..	..	33.95	6.10	Elocon [MK]

■ PANTHENOL**Note** To be used in conjunction with the scalp cleanser salicylic acid with coal tar solution and pine tar (code 4447C).**panthenol conditioner, 200 g**

4510J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	17.23	6.10	SebiRinse [EO]

■ PINE TAR WITH TRIETHANOLAMINE LAURYL SULFATE**Note** For patients who have failed to respond to simple moisturising agents.**PINE TAR with TRIETHANOLAMINE LAURYL SULFATE Solution 23 mg-60 mg per mL (2.3%-6%), 500 mL, 1**

4408B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	2	..	24.77	6.10	Pinetarsol [EO]

