



Australian Government

Department of Health



Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 September 2015



Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 September 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 September 2015. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

General Pharmaceutical Benefits

Additions

Addition – Item

10466W	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN , amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 500 g (<i>XLYS, LOW TRY Maxamum</i>)
10445R	FEBUXOSTAT , febuxostat 80mg tablet, 28 (<i>Adenuric</i>)
10486X	LISDEXAMFETAMINE , lisdexamfetamine dimesilate 30 mg capsule, 30 (<i>Vyvanse</i>)
10474G	LISDEXAMFETAMINE , lisdexamfetamine dimesilate 50 mg capsule, 30 (<i>Vyvanse</i>)
10492F	LISDEXAMFETAMINE , lisdexamfetamine dimesilate 70 mg capsule, 30 (<i>Vyvanse</i>)
10460M	POSACONAZOLE , posaconazole 100 mg tablet: modified release, 24 (<i>Noxafil</i>)
10425Q	SECUKINUMAB , secukinumab 150 mg/mL injection, 2 x 1 mL injection devices (<i>Cosentyx</i>)
10494H	SECUKINUMAB , secukinumab 150 mg/mL injection, 2 x 1 mL injection devices (<i>Cosentyx</i>)
10459L	SUNITINIB , sunitinib 37.5 mg capsule, 28 (<i>Sutent</i>)
10464R	SUNITINIB , sunitinib 37.5 mg capsule, 28 (<i>Sutent</i>)
10473F	SUNITINIB , sunitinib 37.5 mg capsule, 28 (<i>Sutent</i>)
10503T	SUNITINIB , sunitinib 37.5 mg capsule, 28 (<i>Sutent</i>)
10504W	SUNITINIB , sunitinib 37.5 mg capsule, 28 (<i>Sutent</i>)

Addition – Brand

8361C	<i>Capecitabine MYX, YN</i> – CAPECITABINE , capecitabine 150 mg tablet, 60
8362D	<i>Capecitabine MYX, YN</i> – CAPECITABINE , capecitabine 500 mg tablet, 120
8702B	<i>Talam, QA</i> – CITALOPRAM , citalopram 10 mg tablet, 28
8703C	<i>Talam, QA</i> – CITALOPRAM , citalopram 40 mg tablet, 28
8600P	<i>Esomeprazole GH, GQ</i> – ESOMEPRAZOLE , esomeprazole 20 mg tablet: enteric, 30 tablets
8886Q	<i>Esomeprazole GH, GQ</i> – ESOMEPRAZOLE , esomeprazole 20 mg tablet: enteric, 30 tablets
3401B	<i>Esomeprazole GH, GQ</i> – ESOMEPRAZOLE , esomeprazole 40 mg tablet: enteric, 30 tablets
8601Q	<i>Esomeprazole GH, GQ</i> – ESOMEPRAZOLE , esomeprazole 40 mg tablet: enteric, 30 tablets
1526H	<i>APO-Flucloxacillin, TX</i> – FLUCLOXACILLIN , flucloxacillin 250 mg capsule, 24
5090X	<i>APO-Flucloxacillin, TX</i> – FLUCLOXACILLIN , flucloxacillin 250 mg capsule, 24 (Dental)
1527J	<i>APO-Flucloxacillin, TX</i> – FLUCLOXACILLIN , flucloxacillin 500 mg capsule, 24
5091Y	<i>APO-Flucloxacillin, TX</i> – FLUCLOXACILLIN , flucloxacillin 500 mg capsule, 24 (Dental)
9169N	<i>Kerron, DO</i> – LEVETIRACETAM , levetiracetam 100 mg/mL oral liquid, 300 mL

Deletions

Deletion – Item

5514F	FLURBIPROFEN , flurbiprofen sodium 0.03% (120 microgram/0.4 mL) eye drops, 5 x 0.4 mL ampoules (<i>Ocufen</i>) (Optometrical)
8699W	FLURBIPROFEN , flurbiprofen sodium 0.03% (120 microgram/0.4 mL) eye drops, 5 x 0.4 mL ampoules (<i>Ocufen</i>)
9485F	GLUCOSE INDICATOR BLOOD , glucose indicator blood strip: diagnostic, 50 (<i>Lifeline Attest</i>)
9486G	GLUCOSE INDICATOR BLOOD , glucose indicator blood strip: diagnostic, 50 (<i>Lifeline Attest</i>)
10141R	GLUCOSE INDICATOR BLOOD , glucose indicator blood strip: diagnostic, 100 (<i>EasyMate II</i>)
10145Y	GLUCOSE INDICATOR BLOOD , glucose indicator blood strip: diagnostic, 100 (<i>EasyMate II</i>)
3064G	LACTULOSE , LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1 (<i>Actilax, Dulose</i>)
8834Y	METHYLPREDNISOLONE , methylprednisolone 1 g injection [1 x 1 g vial] (&) inert substance diluent [1 x 16 mL vial], 1 pack (<i>Solu-Medrol</i>)
8209C	PAMIDRONATE DISODIUM , pamidronate disodium 30 mg injection [2 x 30 mg vials] (&) inert substance diluent [2 x 10 mL ampoules], 1 pack (<i>Aredia 30 mg</i>)
2476H	RIVASTIGMINE , rivastigmine 2 mg/mL oral liquid, 120 mL (<i>Exelon</i>)
8563Q	RIVASTIGMINE , rivastigmine 2 mg/mL oral liquid, 120 mL (<i>Exelon</i>)

Deletion – Brand

1052J	<i>Acihexal, SZ</i> – ACICLOVIR , aciclovir 800 mg tablet, 35
8234J	<i>Acihexal, SZ</i> – ACICLOVIR , aciclovir 800 mg tablet, 120

Deletion – Equivalence Indicator

8234J	<i>Acyclo-V 800, AF</i> – ACICLOVIR , aciclovir 800 mg tablet, 120
8462J	<i>Pamisol, HH</i> – PAMIDRONATE DISODIUM , pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial

Alterations

Alteration – Restriction

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

8357W	ACAMPROSATE , acamprosate calcium 333 mg tablet: enteric, 180 tablets (<i>Campral</i>)
9425C	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Humira</i>)
9426D	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (<i>Humira</i>)
9427E	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes (<i>Humira</i>)
9428F	ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges (<i>Humira</i>)
3016R	AMANTADINE , amantadine hydrochloride 100 mg capsule, 100 (<i>Symmetrel 100</i>)
2646G	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN , amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 500 g (<i>XLYS, LOW TRY Maxamaid</i>)
2650L	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN , amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 400 g (<i>GA1 Anamix infant</i>)
5484P	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN , amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 30 x 25 g sachets (<i>GA express 15</i>)
9438R	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN , amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 30 x 24 g sachets (<i>GA gel</i>)
8604W	BISOPROLOL , bisoprolol fumarate 2.5 mg tablet, 28 (<i>APO-Bisoprolol, Beprol 2.5, Bicard 2.5, Bicolor, Biso 2.5, Bisoprolol AN, Bisoprolol Sandoz, Bisoprolol generichealth, Bispro 2.5, Chem mart Bisoprolol, Terry White Chemists Bisoprolol</i>)
8605X	BISOPROLOL , bisoprolol fumarate 5 mg tablet, 28 (<i>APO-Bisoprolol, Beprol 5, Bicard 5, Bicolor, Biso 5, Bisoprolol AN, Bisoprolol Sandoz, Bisoprolol generichealth, Bispro 5, Chem mart Bisoprolol, Terry White Chemists Bisoprolol</i>)
8606Y	BISOPROLOL , bisoprolol fumarate 10 mg tablet, 28 (<i>APO-Bisoprolol, Beprol 10, Bicard 10, Bicolor, Biso 10, Bisoprolol AN, Bisoprolol Sandoz, Bisoprolol generichealth, Bispro 10, Chem mart Bisoprolol, Terry White Chemists Bisoprolol</i>)

1443Y	BROMOCRIPTINE , bromocriptine 2.5 mg tablet, 30 (<i>Parlodel</i>)
1444B	BROMOCRIPTINE , bromocriptine 2.5 mg tablet, 30 (<i>Krypton 2.5, Parlodel</i>)
1559C	BROMOCRIPTINE , bromocriptine 2.5 mg tablet, 60 (<i>Krypton 2.5</i>)
8114C	CABERGOLINE , cabergoline 500 microgram tablet, 8 (<i>Dostan, Dostinex</i>)
8115D	CABERGOLINE , cabergoline 500 microgram tablet, 2 (<i>Dostan, Dostinex</i>)
8393R	CABERGOLINE , cabergoline 1 mg tablet, 30 (<i>Cabaser, Cobasol</i>)
8394T	CABERGOLINE , cabergoline 2 mg tablet, 30 (<i>Cabaser, Cobasol</i>)
2502Q	CALCITRIOL , calcitriol 0.25 microgram capsule, 100 (<i>Calciprox, Calcitriol AN, Calcitriol Sandoz, Calcitriol-GA, GenRx Calcitriol, Kosteo, Rocaltrol, Sical</i>)
8255L	CARVEDILOL , carvedilol 3.125 mg tablet, 30 (<i>APO-Carvedilol, Carvedilol AN, Chem mart Carvedilol 3.125 mg, Dilatrend 3.125, GN-Carvedilol, Terry White Chemists Carvedilol 3.125 mg, Vedilol 3.125, Volirop 3.125</i>)
8256M	CARVEDILOL , carvedilol 6.25 mg tablet, 60 (<i>APO-Carvedilol, Carvedilol AN, Carvedilol Sandoz, Carvedilol generichealth, Chem mart Carvedilol 6.25 mg, Dicarz, Dilatrend 6.25, GN-Carvedilol, Terry White Chemists Carvedilol 6.25 mg, Vedilol 6.25, Volirop 6.25</i>)
8257N	CARVEDILOL , carvedilol 12.5 mg tablet, 60 (<i>APO-Carvedilol, Carvedilol AN, Carvedilol Sandoz, Carvedilol generichealth, Chem mart Carvedilol 12.5 mg, Dicarz, Dilatrend 12.5, GN-Carvedilol, Terry White Chemists Carvedilol 12.5 mg, Vedilol 12.5, Volirop 12.5</i>)
8258P	CARVEDILOL , carvedilol 25 mg tablet, 60 (<i>APO-Carvedilol, Carvedilol AN, Carvedilol Sandoz, Carvedilol generichealth, Chem mart Carvedilol 25 mg, Dicarz, Dilatrend 25, GN-Carvedilol, Terry White Chemists Carvedilol 25 mg, Vedilol 25, Volirop 25</i>)
8220P	CITALOPRAM , citalopram 20 mg tablet, 28 (<i>APO-Citalopram, Auro-Citalopram 20, Celapram, Celica, Chem mart Citalopram, Ciazil, Cipramil, Citalopram AN, Citalopram Actavis, Citalopram Sandoz, Citalopram generichealth, Citalopram-GA, Pharmacor Citalo 20, Talam, Terry White Chemists Citalopram</i>)
8702B	CITALOPRAM , citalopram 10 mg tablet, 28 (<i>Celapram, Citalopram Actavis, Citalopram-GA, Talam</i>)
8703C	CITALOPRAM , citalopram 40 mg tablet, 28 (<i>APO-Citalopram, Auro-Citalopram 40, Celapram, Citalopram AN, Citalopram Actavis, Citalopram Sandoz, Citalopram-GA, Talam</i>)
2129C	DESMOPRESSIN , desmopressin acetate 100 microgram/mL nasal drops, 2.5 mL (<i>Minirin</i>)
8662X	DESMOPRESSIN , desmopressin acetate 200 microgram tablet, 30 (<i>Minirin</i>)
8663Y	DESMOPRESSIN , desmopressin acetate 200 microgram tablet, 30 (<i>Minirin</i>)
8711L	DESMOPRESSIN , desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations (<i>Minirin Nasal Spray</i>)
8712M	DESMOPRESSIN , desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations (<i>Minirin Nasal Spray</i>)
8975J	DESMOPRESSIN , desmopressin 240 microgram wafer: sublingual, 30 (<i>Minirin Melt</i>)
9398P	DESMOPRESSIN , desmopressin 120 microgram wafer: sublingual, 30 (<i>Minirin Melt</i>)
5096F	DICLOXACILLIN , dicloxacillin 250 mg capsule, 24 (<i>Distaph 250</i>)(Dental)
5097G	DICLOXACILLIN , dicloxacillin 500 mg capsule, 24 (<i>Distaph 500</i>)(Dental)
8121K	DICLOXACILLIN , dicloxacillin 250 mg capsule, 24 (<i>Distaph 250</i>)
8122L	DICLOXACILLIN , dicloxacillin 500 mg capsule, 24 (<i>Distaph 500</i>)
5290K	ELETRIPTAN , eletriptan 40 mg tablet, 4 (<i>Relpax</i>)
5291L	ELETRIPTAN , eletriptan 80 mg tablet, 4 (<i>Relpax</i>)
8367J	ENTACAPONE , entacapone 200 mg tablet, 100 (<i>Comtan</i>)
9037P	ETANERCEPT , etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (<i>Enbrel</i>)
9091L	ETANERCEPT , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (<i>Enbrel</i>)
9429G	ETANERCEPT , etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack (<i>Enbrel</i>)
9431J	ETANERCEPT , ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1 (<i>Enbrel</i>)
9461Y	ETANERCEPT , ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (<i>Enbrel</i>)
9462B	ETANERCEPT , ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1 (<i>Enbrel</i>)
1524F	FLUCLOXACILLIN , flucloxacillin 500 mg injection, 5 x 500 mg vials (<i>Flubiclox, Flucil</i>)

1525G	FLUCLOXACILLIN , flucloxacillin 1 g injection, 5 x 1 g vials (<i>Flubiclox, Flucil, Hospira Pty Limited</i>)
1526H	FLUCLOXACILLIN , flucloxacillin 250 mg capsule, 24 (<i>APO-Flucloxacillin, Flopen, Staphylex 250</i>)
1527J	FLUCLOXACILLIN , flucloxacillin 500 mg capsule, 24 (<i>APO-Flucloxacillin, Flopen, Staphylex 500</i>)
5090X	FLUCLOXACILLIN , flucloxacillin 250 mg capsule, 24 (<i>APO-Flucloxacillin, Flopen, Staphylex 250</i>)(Dental)
5091Y	FLUCLOXACILLIN , flucloxacillin 500 mg capsule, 24 (<i>APO-Flucloxacillin, Flopen, Staphylex 500</i>)(Dental)
5094D	FLUCLOXACILLIN , flucloxacillin 500 mg injection, 5 x 500 mg vials (<i>Flubiclox, Flucil</i>)(Dental)
5095E	FLUCLOXACILLIN , flucloxacillin 1 g injection, 5 x 1 g vials (<i>Flubiclox, Flucil, Hospira Pty Limited</i>)(Dental)
5257Q	FLUCLOXACILLIN , flucloxacillin 125 mg/5 mL oral liquid: powder for, 100 mL (<i>Flucil</i>)(Dental)
5258R	FLUCLOXACILLIN , flucloxacillin 250 mg/5 mL oral liquid: powder for, 100 mL (<i>Flucil</i>)(Dental)
9149M	FLUCLOXACILLIN , flucloxacillin 125 mg/5 mL oral liquid: powder for, 100 mL (<i>Flucil</i>)
9150N	FLUCLOXACILLIN , flucloxacillin 250 mg/5 mL oral liquid: powder for, 100 mL (<i>Flucil</i>)
1834M	GABAPENTIN , gabapentin 300 mg capsule, 100 (<i>Gabacor, Gabapentin Aspen 300, Gabapentin GH, Gabapentin Sandoz, Gabapentin-GA, Gantin, GenRx Gabapentin, Neurontin, Nupentin 300</i>)
1835N	GABAPENTIN , gabapentin 400 mg capsule, 100 (<i>Gabacor, Gabapentin Aspen 400, Gabapentin GH, Gabapentin Sandoz, Gantin, GenRx Gabapentin, Neurontin, Nupentin 400</i>)
8389M	GABAPENTIN , gabapentin 800 mg tablet, 100 (<i>Gabapentin AN, Gabapentin Aspen 800, Gabaran, Gantin, GenRx Gabapentin, Neurontin, Nupentin Tabs, Pharmacor Gabapentin 800</i>)
8505P	GABAPENTIN , gabapentin 100 mg capsule, 100 (<i>APO-Gabapentin, Gabacor, Gabapentin Aspen 100, Neurontin, Nupentin 100</i>)
8559L	GABAPENTIN , gabapentin 600 mg tablet, 100 (<i>Gabapentin AN, Gabapentin Aspen 600, Gabaran, GenRx Gabapentin, Neurontin, Nupentin Tabs, Pharmacor Gabapentin 600</i>)
9040T	INSULIN DETEMIR , insulin detemir 100 international units/mL injection, 5 x 3 mL cartridges (<i>Levemir FlexPen, Levemir Penfill</i>)
2549E	ISOTRETINOIN , isotretinoin 40 mg capsule, 30 (<i>Dermatane, Oratane</i>)
2591J	ISOTRETINOIN , isotretinoin 10 mg capsule, 60 (<i>APO-Isotretinoin, Dermatane, Isotretinoin AN, Isotretinoin SCP 10, Oratane, Roaccutane, Rocta 10</i>)
2592K	ISOTRETINOIN , isotretinoin 20 mg capsule, 60 (<i>APO-Isotretinoin, Dermatane, Isotretinoin AN, Isotretinoin SCP 20, Oratane, Roaccutane, Rocta 20</i>)
2848X	LAMOTRIGINE , lamotrigine 25 mg tablet, 56 (<i>APO-Lamotrigine, GenRx Lamotrigine, Lamictal, Lamidus, Lamogine, Lamotrigine AN, Lamotrigine Aspen 25, Lamotrigine Sandoz, Lamotrigine generichealth, Lamotrigine-GA, Lamotrust 25, Logem, Reedos 25, Seaze 25, Torlemo DT 25</i>)
2849Y	LAMOTRIGINE , lamotrigine 50 mg tablet, 56 (<i>APO-Lamotrigine, GenRx Lamotrigine, Lamictal, Lamidus, Lamogine, Lamotrigine AN, Lamotrigine Aspen 50, Lamotrigine Sandoz, Lamotrigine generichealth, Lamotrigine-GA, Lamotrust 50, Logem, Reedos 50, Seaze 50, Torlemo DT 50</i>)
2850B	LAMOTRIGINE , lamotrigine 100 mg tablet, 56 (<i>APO-Lamotrigine, GenRx Lamotrigine, Lamictal, Lamidus, Lamogine, Lamotrigine AN, Lamotrigine Aspen 100, Lamotrigine Sandoz, Lamotrigine generichealth, Lamotrigine-GA, Lamotrust 100, Logem, Reedos 100, Seaze 100, Torlemo DT 100</i>)
2851C	LAMOTRIGINE , lamotrigine 200 mg tablet, 56 (<i>APO-Lamotrigine, GenRx Lamotrigine, Lamictal, Lamidus, Lamogine, Lamotrigine AN, Lamotrigine Aspen 200, Lamotrigine Sandoz, Lamotrigine generichealth, Lamotrigine-GA, Lamotrust 200, Logem, Reedos 200, Seaze 200, Torlemo DT 200</i>)
8063J	LAMOTRIGINE , lamotrigine 5 mg tablet, 56 (<i>Lamictal, Lamogine, Lamotrigine Aspen 5, Seaze 5</i>)
8654L	LEVETIRACETAM , levetiracetam 250 mg tablet, 60 (<i>APO-Levetiracetam, Chem mart Levetiracetam, Kepcet, Keppra, Kerron 250, Kevtam, Levactam, Levecetam 250, Levetiracetam AN, Levetiracetam SZ, Levetiracetam generichealth, Levi 250, Levitaccord, Levitam 250, Terry White Chemists Levetiracetam</i>)
8655M	LEVETIRACETAM , levetiracetam 500 mg tablet, 60 (<i>APO-Levetiracetam, Chem mart Levetiracetam, Kepcet, Keppra, Kerron 500, Kevtam, Levactam, Levecetam 500, Levetiracetam AN, Levetiracetam SZ, Levetiracetam generichealth, Levi 500, Levitaccord, Levitam 500, Terry White Chemists Levetiracetam</i>)
8656N	LEVETIRACETAM , levetiracetam 1 g tablet, 60 (<i>APO-Levetiracetam, Chem mart Levetiracetam, Kepcet, Keppra, Kerron 1000, Kevtam, Levactam, Levecetam 1000, Levetiracetam AN, Levetiracetam SZ, Levetiracetam generichealth, Levi 1000, Levitaccord, Levitam 1000, Terry White Chemists Levetiracetam</i>)
9169N	LEVETIRACETAM , levetiracetam 100 mg/mL oral liquid, 300 mL (<i>Keppra, Kerron, Levetiracetam-AFT</i>)
1255C	LEVODOPA + CARBIDOPA ANHYDROUS , levodopa 200 mg + carbidopa anhydrous 50 mg tablet: modified release, 100 tablets (<i>Sinemet CR</i>)

8797B	LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE , levodopa 50 mg + carbidopa anhydrous 12.5 mg + entacapone 200 mg tablet, 100 (<i>Stalevo 50/12.5/200mg</i>)
8798C	LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE , levodopa 100 mg + carbidopa anhydrous 25 mg + entacapone 200 mg tablet, 100 (<i>Stalevo 100/25/200mg</i>)
8799D	LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE , levodopa 150 mg + carbidopa anhydrous 37.5 mg + entacapone 200 mg tablet, 100 (<i>Stalevo 150/37.5/200mg</i>)
9292C	LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE , levodopa 200 mg + carbidopa anhydrous 50 mg + entacapone 200 mg tablet, 100 (<i>Stalevo 200/50/200mg</i>)
9344T	LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE , levodopa 75 mg + carbidopa anhydrous 18.75 mg + entacapone 200 mg tablet, 100 (<i>Stalevo 75/18.75/200mg</i>)
9345W	LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE , levodopa 125 mg + carbidopa anhydrous 31.25 mg + entacapone 200 mg tablet, 100 (<i>Stalevo 125/31.25/200mg</i>)
8633J	LEVONORGESTREL , levonorgestrel 52 mg drug delivery system: intrauterine, 1 system (<i>Mirena</i>)
5146W	MAGNESIUM ASPARTATE DIHYDRATE , magnesium aspartate dihydrate 500 mg (equivalent to 37.4 mg of magnesium) tablet, 50 (<i>Mag-Sup, MagMin (PBS)</i>)
5264C	METHYLPREDNISOLONE , methylprednisolone Powder for injection 1 g (as sodium succinate), 1 (<i>Methylpred, Methylprednisolone Alphapharm, Solu-Medrol</i>)
8732N	METOPROLOL SUCCINATE , METOPROLOL SUCCINATE Tablet 23.75 mg (controlled release), 15 (<i>Metrol-XL 23.75, Minax XL, Toprol-XL 23.75</i>)
8733P	METOPROLOL SUCCINATE , METOPROLOL SUCCINATE Tablet 47.5 mg (controlled release), 30 (<i>Metrol-XL 47.5, Minax XL, Toprol-XL 47.5</i>)
8734Q	METOPROLOL SUCCINATE , METOPROLOL SUCCINATE Tablet 95 mg (controlled release), 30 (<i>Metrol-XL 95, Minax XL, Toprol-XL 95</i>)
8735R	METOPROLOL SUCCINATE , METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30 (<i>Metrol-XL 190, Minax XL, Toprol-XL 190</i>)
2313R	MINOXIDIL , minoxidil 10 mg tablet, 100 (<i>Loniten</i>)
2962X	NAFARELIN , nafarelin 200 microgram/actuation nasal spray, 60 actuations (<i>Synarel</i>)
8370M	NALTREXONE , naltrexone hydrochloride 50 mg tablet, 30 (<i>Naltrexone GH, ReVia</i>)
1671Y	NANDROLONE DECANOATE , nandrolone decanoate 50 mg/mL injection, 1 x 1 mL syringe (<i>Deca-Durabolin</i>)
9311C	NEBIVOLOL , nebivolol 5 mg tablet, 28 (<i>Nebilet</i>)
9312D	NEBIVOLOL , nebivolol 10 mg tablet, 28 (<i>Nebilet</i>)
9316H	NEBIVOLOL , nebivolol 1.25 mg tablet, 28 (<i>Nebilet</i>)
10076H	NICOTINE , nicotine 25 mg/16 hours patch, 28 (<i>nicorette 16hr Invisipatch</i>)
3414Q	NICOTINE , nicotine 21 mg/24 hours patch, 28 (<i>Nicotinell Step 1</i>)
5465P	NICOTINE , nicotine 21 mg/24 hours patch, 28 (<i>Nicabate P</i>)
5571F	NICOTINE , nicotine 21 mg/24 hours patch, 28 (<i>Nicotinell Step 1</i>)
5572G	NICOTINE , nicotine 14 mg/24 hours patch, 28 (<i>Nicotinell Step 2</i>)
5573H	NICOTINE , nicotine 7 mg/24 hours patch, 28 (<i>Nicotinell Step 3</i>)
8584T	OXCARBAZEPINE , oxcarbazepine 150 mg tablet, 100 (<i>Trileptal</i>)
8585W	OXCARBAZEPINE , oxcarbazepine 300 mg tablet, 100 (<i>Trileptal</i>)
8586X	OXCARBAZEPINE , oxcarbazepine 600 mg tablet, 100 (<i>Trileptal</i>)
8588B	OXCARBAZEPINE , oxcarbazepine 60 mg/mL oral liquid, 250 mL (<i>Trileptal</i>)
8462J	PAMIDRONATE DISODIUM , pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial (<i>Pamisol</i>)
3418X	PRAMIPEXOLE , pramipexole hydrochloride monohydrate 375 microgram tablet: modified release, 30 tablets (<i>Sifrol ER</i>)
3419Y	PRAMIPEXOLE , pramipexole hydrochloride monohydrate 750 microgram tablet: modified release, 30 tablets (<i>Sifrol ER</i>)
3420B	PRAMIPEXOLE , pramipexole hydrochloride monohydrate 1.5 mg tablet: modified release, 30 tablets (<i>Sifrol ER</i>)
3421C	PRAMIPEXOLE , pramipexole hydrochloride monohydrate 3 mg tablet: modified release, 30 tablets (<i>Sifrol ER</i>)

3422D	PRAMIPEXOLE , pramipexole hydrochloride monohydrate 4.5 mg tablet: modified release, 30 tablets (<i>Sifrol ER</i>)
5143Q	PRAMIPEXOLE , pramipexole hydrochloride monohydrate 2.25 mg tablet: modified release, 30 tablets (<i>Sifrol ER</i>)
5145T	PRAMIPEXOLE , pramipexole hydrochloride monohydrate 3.75 mg tablet: modified release, 30 tablets (<i>Sifrol ER</i>)
9151P	PRAMIPEXOLE , pramipexole hydrochloride monohydrate 125 microgram tablet, 30 (<i>APO-Pramipexole, Pramipexole AN, Pramipexole GH, Sifrol, Simipex 0.125, Simpral</i>)
9152Q	PRAMIPEXOLE , pramipexole hydrochloride monohydrate 250 microgram tablet, 100 (<i>APO-Pramipexole, Pramipexole AN, Pramipexole GH, Sifrol, Simipex 0.25, Simpral</i>)
9153R	PRAMIPEXOLE , pramipexole hydrochloride monohydrate 1 mg tablet, 100 (<i>APO-Pramipexole, Pramipexole AN, Pramipexole GH, Sifrol, Simipex 1, Simpral</i>)
9393J	PRAMIPEXOLE , pramipexole hydrochloride monohydrate 125 microgram tablet, 30 (<i>Sifrol</i>)
9394K	PRAMIPEXOLE , pramipexole hydrochloride monohydrate 250 microgram tablet, 100 (<i>Sifrol</i>)
8822H	QUINAGOLIDE , quinagolide 75 microgram tablet, 30 (<i>Norprolac</i>)
8860H	QUINAGOLIDE , quinagolide 25 microgram tablet [3 tablets] (&) quinagolide 50 microgram tablet [3 tablets], 6 (<i>Norprolac</i>)
1952R	RASAGILINE , RASAGILINE Tablet 1 mg (as mesilate), 30 (<i>Azilect</i>)
8664B	RILUZOLE , riluzole 50 mg tablet, 56 (<i>APO-Riluzole, Pharmacor Riluzole, Rilutek, Riluzole Sandoz</i>)
9313E	RIZATRIPTAN , rizatriptan 10 mg wafer, 2 (<i>Maxalt</i>)
2997R	SALCATONIN , salcatonin 100 international units/mL injection, 5 x 1 mL ampoules (<i>Miacalcic 100</i>)
1973W	SELEGILINE , selegiline hydrochloride 5 mg tablet, 100 (<i>Eldepryl, Selgene</i>)
1849H	SUMATRIPTAN , sumatriptan 50 mg tablet, 4 (<i>APO-Sumatriptan, Chem mart Sumatriptan, Iptam, Pharmacor Sumatriptan 50, Sumatran, Sumatriptan AN, Sumatriptan RBX, Sumatriptan Sandoz, Sumatriptan generichealth, Sumatriptan-GA, Terry White Chemists Sumatriptan</i>)
8144P	SUMATRIPTAN , SUMATRIPTAN Tablet 50 mg (as succinate), 2 (<i>APO-Sumatriptan, Chem mart Sumatriptan, Imigran, Iptam, Sumagran Aspen 50, Sumatab, Sumatran, Sumatriptan Sandoz, Terry White Chemists Sumatriptan</i>)
8341B	SUMATRIPTAN , sumatriptan 20 mg/actuation nasal spray, 2 actuations (<i>Imigran</i>)
8885P	SUMATRIPTAN , SUMATRIPTAN Tablet (fast disintegrating) 50 mg (as succinate), 2 (<i>Imigran FDT</i>)
9488J	SUNITINIB , sunitinib 12.5 mg capsule, 28 (<i>Sutent</i>)
9489K	SUNITINIB , sunitinib 25 mg capsule, 28 (<i>Sutent</i>)
9490L	SUNITINIB , sunitinib 50 mg capsule, 28 (<i>Sutent</i>)
1330B	TETRABENAZINE , tetrabenazine 25 mg tablet, 112 (<i>iNova Pharmaceuticals (Australia) Pty Ltd</i>)
1070H	THIAMINE , thiamine hydrochloride 100 mg tablet, 100 (<i>Betavit</i>)
2700D	THYROTROPIN ALFA , thyrotropin alfa 900 microgram injection, 2 x 900 microgram vials (<i>Thyrogen</i>)
8163P	TOPIRAMATE , topiramate 25 mg tablet, 60 (<i>APO-Topiramate, Epiramax 25, RBX Topiramate, Tamate, Topamax, Topiramate AN, Topiramate GH, Topiramate Sandoz</i>)
8164Q	TOPIRAMATE , topiramate 50 mg tablet, 60 (<i>APO-Topiramate, Epiramax 50, RBX Topiramate, Tamate, Topamax, Topiramate AN, Topiramate GH, Topiramate Sandoz</i>)
8165R	TOPIRAMATE , topiramate 100 mg tablet, 60 (<i>APO-Topiramate, Epiramax 100, RBX Topiramate, Tamate, Topamax, Topiramate AN, Topiramate GH, Topiramate Sandoz</i>)
8166T	TOPIRAMATE , topiramate 200 mg tablet, 60 (<i>APO-Topiramate, Epiramax 200, RBX Topiramate, Tamate, Topamax, Topiramate AN, Topiramate GH, Topiramate Sandoz</i>)
8371N	TOPIRAMATE , topiramate 15 mg capsule, 60 (<i>Topamax Sprinkle</i>)
8372P	TOPIRAMATE , topiramate 25 mg capsule, 60 (<i>Topamax Sprinkle</i>)
8520K	TOPIRAMATE , topiramate 50 mg capsule, 60 (<i>Topamax Sprinkle</i>)
9304Q	USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 1 x 0.5 mL vial (<i>Stelara</i>)
9305R	USTEKINUMAB , ustekinumab 45 mg/0.5 mL injection, 1 x 0.5 mL vial (<i>Stelara</i>)
9388D	ZONISAMIDE , zonisamide 25 mg capsule, 56 (<i>Zonegran</i>)
9389E	ZONISAMIDE , zonisamide 50 mg capsule, 56 (<i>Zonegran</i>)
9390F	ZONISAMIDE , zonisamide 100 mg capsule, 56 (<i>Zonegran</i>)

Alteration – Restriction Level

		From	To
8604W	BISOPROLOL , bisoprolol fumarate 2.5 mg tablet, 28 (APO-Bisoprolol, Beprol 2.5, Bicard 2.5, Bicor, Biso 2.5, Bisoprolol AN, Bisoprolol Sandoz, Bisoprolol generichealth, Bispro 2.5, Chem mart Bisoprolol, Terry White Chemists Bisoprolol)	streamlined	restricted
8605X	BISOPROLOL , bisoprolol fumarate 5 mg tablet, 28 (APO-Bisoprolol, Beprol 5, Bicard 5, Bicor, Biso 5, Bisoprolol AN, Bisoprolol Sandoz, Bisoprolol generichealth, Bispro 5, Chem mart Bisoprolol, Terry White Chemists Bisoprolol)	streamlined	restricted
8606Y	BISOPROLOL , bisoprolol fumarate 10 mg tablet, 28 (APO-Bisoprolol, Beprol 10, Bicard 10, Bicor, Biso 10, Bisoprolol AN, Bisoprolol Sandoz, Bisoprolol generichealth, Bispro 10, Chem mart Bisoprolol, Terry White Chemists Bisoprolol)	streamlined	restricted
8114C	CABERGOLINE , cabergoline 500 microgram tablet, 8 (Dostan, Dostinex)	streamlined	restricted
8255L	CARVEDILOL , carvedilol 3.125 mg tablet, 30 (APO-Carvedilol, Carvedilol AN, Chem mart Carvedilol 3.125 mg, Dilatrend 3.125, GN-Carvedilol, Terry White Chemists Carvedilol 3.125 mg, Vedilol 3.125, Volirop 3.125)	streamlined	restricted
8256M	CARVEDILOL , carvedilol 6.25 mg tablet, 60 (APO-Carvedilol, Carvedilol AN, Carvedilol Sandoz, Carvedilol generichealth, Chem mart Carvedilol 6.25 mg, Dicarz, Dilatrend 6.25, GN-Carvedilol, Terry White Chemists Carvedilol 6.25 mg, Vedilol 6.25, Volirop 6.25)	streamlined	restricted
8257N	CARVEDILOL , carvedilol 12.5 mg tablet, 60 (APO-Carvedilol, Carvedilol AN, Carvedilol Sandoz, Carvedilol generichealth, Chem mart Carvedilol 12.5 mg, Dicarz, Dilatrend 12.5, GN-Carvedilol, Terry White Chemists Carvedilol 12.5 mg, Vedilol 12.5, Volirop 12.5)	streamlined	restricted
8258P	CARVEDILOL , carvedilol 25 mg tablet, 60 (APO-Carvedilol, Carvedilol AN, Carvedilol Sandoz, Carvedilol generichealth, Chem mart Carvedilol 25 mg, Dicarz, Dilatrend 25, GN-Carvedilol, Terry White Chemists Carvedilol 25 mg, Vedilol 25, Volirop 25)	streamlined	restricted
5290K	ELETRIPTAN , eletriptan 40 mg tablet, 4 (Relpax)	streamlined	restricted
5291L	ELETRIPTAN , eletriptan 80 mg tablet, 4 (Relpax)	streamlined	restricted
8367J	ENTACAPONE , entacapone 200 mg tablet, 100 (Comtan)	streamlined	restricted
1255C	LEVODOPA + CARBIDOPA ANHYDROUS , levodopa 200 mg + carbidopa anhydrous 50 mg tablet: modified release, 100 tablets (Sinemet CR)	streamlined	restricted
8797B	LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE , levodopa 50 mg + carbidopa anhydrous 12.5 mg + entacapone 200 mg tablet, 100 (Stalevo 50/12.5/200mg)	streamlined	restricted
8798C	LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE , levodopa 100 mg + carbidopa anhydrous 25 mg + entacapone 200 mg tablet, 100 (Stalevo 100/25/200mg)	streamlined	restricted
8799D	LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE , levodopa 150 mg + carbidopa anhydrous 37.5 mg + entacapone 200 mg tablet, 100 (Stalevo 150/37.5/200mg)	streamlined	restricted
9292C	LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE , levodopa 200 mg + carbidopa anhydrous 50 mg + entacapone 200 mg tablet, 100 (Stalevo 200/50/200mg)	streamlined	restricted
9344T	LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE , levodopa 75 mg + carbidopa anhydrous 18.75 mg + entacapone 200 mg tablet, 100 (Stalevo 75/18.75/200mg)	streamlined	restricted
9345W	LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE , levodopa 125 mg + carbidopa anhydrous 31.25 mg + entacapone 200 mg tablet, 100 (Stalevo 125/31.25/200mg)	streamlined	restricted
8732N	METOPROLOL SUCCINATE , METOPROLOL SUCCINATE Tablet 23.75 mg (controlled release), 15 (Metrol-XL 23.75, Minax XL, Toprol-XL 23.75)	streamlined	restricted
8733P	METOPROLOL SUCCINATE , METOPROLOL SUCCINATE Tablet 47.5 mg (controlled release), 30 (Metrol-XL 47.5, Minax XL, Toprol-XL 47.5)	streamlined	restricted
8734Q	METOPROLOL SUCCINATE , METOPROLOL SUCCINATE Tablet 95 mg (controlled release), 30 (Metrol-XL 95, Minax XL, Toprol-XL 95)	streamlined	restricted
8735R	METOPROLOL SUCCINATE , METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30 (Metrol-XL 190, Minax XL, Toprol-XL 190)	streamlined	restricted
2313R	MINOXIDIL , minoxidil 10 mg tablet, 100 (Loniten)	streamlined	restricted
9311C	NEBIVOLOL , nebivolol 5 mg tablet, 28 (Nebilet)	streamlined	restricted

9312D	NEBIVOLOL , nebivolol 10 mg tablet, 28 (<i>Nebilet</i>)	streamlined	restricted
9316H	NEBIVOLOL , nebivolol 1.25 mg tablet, 28 (<i>Nebilet</i>)	streamlined	restricted
10076H	NICOTINE , nicotine 25 mg/16 hours patch, 28 (<i>nicorette 16hr Invisipatch</i>)	streamlined	restricted
3414Q	NICOTINE , nicotine 21 mg/24 hours patch, 28 (<i>Nicotinell Step 1</i>)	streamlined	restricted
5465P	NICOTINE , nicotine 21 mg/24 hours patch, 28 (<i>Nicabate P</i>)	streamlined	restricted
5571F	NICOTINE , nicotine 21 mg/24 hours patch, 28 (<i>Nicotinell Step 1</i>)	streamlined	restricted
5572G	NICOTINE , nicotine 14 mg/24 hours patch, 28 (<i>Nicotinell Step 2</i>)	streamlined	restricted
5573H	NICOTINE , nicotine 7 mg/24 hours patch, 28 (<i>Nicotinell Step 3</i>)	streamlined	restricted
8822H	QUINAGOLIDE , quinagolide 75 microgram tablet, 30 (<i>Norprolac</i>)	streamlined	restricted
8860H	QUINAGOLIDE , quinagolide 25 microgram tablet [3 tablets] (&) quinagolide 50 microgram tablet [3 tablets], 6 (<i>Norprolac</i>)	streamlined	restricted
1952R	RASAGILINE , RASAGILINE Tablet 1 mg (as mesilate), 30 (<i>Azilect</i>)	streamlined	restricted
9313E	RIZATRIPTAN , rizatriptan 10 mg wafer, 2 (<i>Maxalt</i>)	streamlined	restricted
2997R	SALCATONIN , salcatonin 100 international units/mL injection, 5 x 1 mL ampoules (<i>Miacalcic 100</i>)	streamlined	restricted
1849H	SUMATRIPTAN , sumatriptan 50 mg tablet, 4 (<i>APO-Sumatriptan, Chem mart Sumatriptan, Iptam, Pharmacor Sumatriptan 50, Sumatran, Sumatriptan AN, Sumatriptan RBX, Sumatriptan Sandoz, Sumatriptan generichealth, Sumatriptan-GA, Terry White Chemists Sumatriptan</i>)	streamlined	restricted
8144P	SUMATRIPTAN , SUMATRIPTAN Tablet 50 mg (as succinate), 2 (<i>APO-Sumatriptan, Chem mart Sumatriptan, Imigran, Iptam, Sumagran Aspen 50, Sumatab, Sumatran, Sumatriptan Sandoz, Terry White Chemists Sumatriptan</i>)	streamlined	restricted
8341B	SUMATRIPTAN , sumatriptan 20 mg/actuation nasal spray, 2 actuations (<i>Imigran</i>)	streamlined	restricted
8885P	SUMATRIPTAN , SUMATRIPTAN Tablet (fast disintegrating) 50 mg (as succinate), 2 (<i>Imigran FDT</i>)	streamlined	restricted
2700D	THYROTROPIN ALFA , thyrotropin alfa 900 microgram injection, 2 x 900 microgram vials (<i>Thyrogen</i>)	streamlined	restricted

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
8216K	<i>Fareston</i> – TOREMIFENE , toremifene 60 mg tablet, 30	MK	AS

Advance Notices

1 October 2015

Deletion – Brand

8465M	<i>Prexaton, GN</i> – BUPROPION , bupropion hydrochloride 150 mg tablet: modified release, 30 tablets
8710K	<i>Prexaton, GN</i> – BUPROPION , bupropion hydrochloride 150 mg tablet: modified release, 90 tablets
8023G	<i>Lescol, NV</i> – FLUVASTATIN , fluvastatin 20 mg capsule, 28
8023G	<i>Vastin, NM</i> – FLUVASTATIN , fluvastatin 20 mg capsule, 28
8024H	<i>Lescol, NV</i> – FLUVASTATIN , fluvastatin 40 mg capsule, 28
8024H	<i>Vastin, NM</i> – FLUVASTATIN , fluvastatin 40 mg capsule, 28
9234B	<i>Lescol, NV</i> – FLUVASTATIN , fluvastatin 20 mg capsule, 28
9234B	<i>Vastin, NM</i> – FLUVASTATIN , fluvastatin 20 mg capsule, 28
9235C	<i>Lescol, NV</i> – FLUVASTATIN , fluvastatin 40 mg capsule, 28
9235C	<i>Vastin, NM</i> – FLUVASTATIN , fluvastatin 40 mg capsule, 28

1 December 2015

Deletion – Brand

8613H	<i>PKU Anamix Junior, SB</i> – 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

9395L	TYR Anamix Junior, SB – 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
8745G	MSUD Anamix Junior, SB – 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

Palliative Care

Deletions

Deletion – Item

5387M	LACTULOSE , LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1 (<i>Actilax, Dulose</i>)
5388N	LACTULOSE , LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1 (<i>Actilax, Dulose</i>)

Highly Specialised Drugs Program (Private Hospital)

Deletions

Deletion – Item

9647R	APOMORPHINE , apomorphine hydrochloride 50 mg/10 mL injection: subcutaneous infusion, 5 x 10 mL syringes (<i>Apomine PFS</i>)
6223M	PAMIDRONATE DISODIUM , pamidronate disodium 90 mg injection [1 x 90 mg vial] (&) inert substance diluent [1 x 10 mL ampoule], 1 pack (<i>Aredia 90 mg</i>)
6279L	PAMIDRONATE DISODIUM , pamidronate disodium 30 mg injection [2 x 30 mg vials] (&) inert substance diluent [2 x 10 mL ampoules], 1 pack (<i>Aredia 30 mg</i>)
2378E	TELAPREVIR , telaprevir 375 mg tablet, 42 (<i>Incivo</i>)

Deletion – Equivalence Indicator

6287X	<i>Pamisol, HH</i> – PAMIDRONATE DISODIUM , pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial
6289B	<i>Pamisol, HH</i> – PAMIDRONATE DISODIUM , pamidronate disodium 90 mg/10 mL injection, 1 x 10 mL vial

Alterations

Alteration – Restriction

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

9619G	IBANDRONIC ACID , ibandronic acid 6 mg/6 mL injection, 1 x 6 mL vial (<i>Bondronat</i>)
6496X	INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial (<i>Remicade</i>)
9617E	INFLIXIMAB , infliximab 100 mg injection, 1 x 100 mg vial (<i>Remicade</i>)
6287X	PAMIDRONATE DISODIUM , pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial (<i>Pamisol</i>)
6289B	PAMIDRONATE DISODIUM , pamidronate disodium 90 mg/10 mL injection, 1 x 10 mL vial (<i>Pamisol</i>)
6371H	ZOLEDRONIC ACID , zoledronic acid 4 mg/5 mL injection, 1 x 5 mL vial (<i>Zometa</i>)

Highly Specialised Drugs Program (Public Hospital)

Deletions

Deletion – Item

5611H	APOMORPHINE , apomorphine hydrochloride 50 mg/10 mL injection: subcutaneous infusion, 5 x 10 mL syringes (<i>Apomine PFS</i>)
5703E	PAMIDRONATE DISODIUM , pamidronate disodium 90 mg injection [1 x 90 mg vial] (&) inert substance diluent [1 x 10 mL ampoule], 1 pack (<i>Aredia 90 mg</i>)
5702D	PAMIDRONATE DISODIUM , pamidronate disodium 30 mg injection [2 x 30 mg vials] (&) inert substance diluent [2 x 10 mL ampoules], 1 pack (<i>Aredia 30 mg</i>)

2437G **TELAPREVIR**, telaprevir 375 mg tablet, 42 (*Incivo*)

Deletion – Equivalence Indicator

5668H *Pamisol, HH* – **PAMIDRONATE DISODIUM**, pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial

5670K *Pamisol, HH* – **PAMIDRONATE DISODIUM**, pamidronate disodium 90 mg/10 mL injection, 1 x 10 mL vial

Alterations

Alteration – Restriction

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

5750P **IBANDRONIC ACID**, ibandronic acid 6 mg/6 mL injection, 1 x 6 mL vial (*Bondronat*)

5756Y **INFLIXIMAB**, infliximab 100 mg injection, 1 x 100 mg vial (*Remicade*)

5758C **INFLIXIMAB**, infliximab 100 mg injection, 1 x 100 mg vial (*Remicade*)

5668H **PAMIDRONATE DISODIUM**, pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial (*Pamisol*)

5670K **PAMIDRONATE DISODIUM**, pamidronate disodium 90 mg/10 mL injection, 1 x 10 mL vial (*Pamisol*)

9653C **ZOLEDRONIC ACID**, zoledronic acid 4 mg/5 mL injection, 1 x 5 mL vial (*Zometa*)

Highly Specialised Drugs Program (Community Access)

Deletions

Deletion – Item

10368Q **FOSAMPRENAVIR**, fosamprenavir 50 mg/mL oral liquid, 225 mL (*Telzir*)

Botulinum Toxin Program

Alterations

Alteration – Restriction

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

6103F **BOTULINUM TOXIN TYPE A**, botulinum toxin type A 100 units injection, 1 x 100 units vial (*Botox*)

1152P **CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX**, clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 x 300 units vial (*Dysport*)

6293F **CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX**, clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 x 500 units vial (*Dysport*)

10253P **INCOBOTULINUMTOXINA**, incobotulinumtoxinA 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial (*Xeomin*)

Alteration – Restriction Level

		<i>From</i>	<i>To</i>
6103F	BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 x 100 units vial (<i>Botox</i>)	restricted	streamlined
1152P	CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX , clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 x 300 units vial (<i>Dysport</i>)	restricted	streamlined
6293F	CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX , clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 x 500 units vial (<i>Dysport</i>)	restricted	streamlined
10253P	INCOBOTULINUMTOXINA , incobotulinumtoxinA 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial (<i>Xeomin</i>)	restricted	streamlined

Alteration – Maximum Quantity

		<i>From</i>	<i>To</i>
6103F	BOTULINUM TOXIN TYPE A , botulinum toxin type A 100 units injection, 1 x 100 units vial (<i>Botox</i>)	1	4
1152P	CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX ,	1	4

	clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 x 300 units vial (<i>Dysport</i>)		
6293F	CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX , clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 x 500 units vial (<i>Dysport</i>)	1	2
10253P	INCOBOTULINUMTOXINA , incobotulinumtoxinA 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial (<i>Xeomin</i>)	1	3

Growth Hormone Programme

Additions

Addition – Item

10456H	SOMATROPIN , somatropin 1.8 international units (600 microgram) injection [7 x 600 microgram syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
10477K	SOMATROPIN , somatropin 1.8 international units (600 microgram) injection [7 x 600 microgram syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
10463Q	SOMATROPIN , somatropin 2.4 international units (800 microgram) injection [7 x 800 microgram syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
10479M	SOMATROPIN , somatropin 2.4 international units (800 microgram) injection [7 x 800 microgram syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
10430Y	SOMATROPIN , somatropin 3 international units (1 mg) injection [7 x 1 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
10480N	SOMATROPIN , somatropin 3 international units (1 mg) injection [7 x 1 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
10453E	SOMATROPIN , somatropin 3.6 international units (1.2 mg) injection [7 x 1.2 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
10457J	SOMATROPIN , somatropin 3.6 international units (1.2 mg) injection [7 x 1.2 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
10434E	SOMATROPIN , somatropin 4.2 international units (1.4 mg) injection [7 x 1.4 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
10488B	SOMATROPIN , somatropin 4.2 international units (1.4 mg) injection [7 x 1.4 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
10454F	SOMATROPIN , somatropin 4.8 international units (1.6 mg) injection [7 x 1.6 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
10498M	SOMATROPIN , somatropin 4.8 international units (1.6 mg) injection [7 x 1.6 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
10500P	SOMATROPIN , somatropin 5.4 international units (1.8 mg) injection [7 x 1.8 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
10501Q	SOMATROPIN , somatropin 5.4 international units (1.8 mg) injection [7 x 1.8 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
10428W	SOMATROPIN , somatropin 6 international units (2 mg) injection [7 x 2 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
10472E	SOMATROPIN , somatropin 6 international units (2 mg) injection [7 x 2 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)
10447W	SOMATROPIN , somatropin 12 international units (4 mg) injection [1 x 4 mg vial] (&) inert substance diluent [1 vial], 1 pack (<i>Zomacton</i>)
10452D	SOMATROPIN , somatropin 12 international units (4 mg) injection [1 x 4 mg vial] (&) inert substance diluent [1 vial], 1 pack (<i>Zomacton</i>)
10433D	SOMATROPIN , SOMATROPIN (Recombinant human growth hormone) Injection 8 mg (24 i.u.) vial with 1.37 mL diluent cartridge (with preservative) (for use with one.click auto-injector), 1 (<i>Saizen 8 mg click.easy</i>)
10471D	SOMATROPIN , SOMATROPIN (Recombinant human growth hormone) Injection 8 mg (24 i.u.) vial with 1.37 mL diluent cartridge (with preservative) (for use with one.click auto-injector), 1 (<i>Saizen 8 mg click.easy</i>)
10440L	SOMATROPIN , somatropin 30 international units (10 mg) injection [1 x 10 mg vial] (&) inert substance diluent [1 x 1 mL syringe], 1 pack (<i>Zomacton</i>)

10455G	SOMATROPIN , somatropin 30 international units (10 mg) injection [1 x 10 mg vial] (& inert substance diluent [1 x 1 mL syringe], 1 pack (<i>Zomacton</i>)
10444Q	SOMATROPIN , somatropin 36 international units (12 mg) injection [1 x 12 mg cartridge] (& inert substance diluent [1 x 1 mL cartridge], 1 pack (<i>Genotropin</i>)
10499N	SOMATROPIN , somatropin 36 international units (12 mg) injection [1 x 12 mg cartridge] (& inert substance diluent [1 x 1 mL cartridge], 1 pack (<i>Genotropin</i>)
10429X	SOMATROPIN , somatropin 18 international units (6 mg) injection [1 x 6 mg cartridge] (& inert substance diluent [1 x 3.15 mL syringe], 1 pack (<i>Humatrope</i>)
10482Q	SOMATROPIN , somatropin 18 international units (6 mg) injection [1 x 6 mg cartridge] (& inert substance diluent [1 x 3.15 mL syringe], 1 pack (<i>Humatrope</i>)
10461N	SOMATROPIN , somatropin 36 international units (12 mg) injection [1 x 12 mg cartridge] (& inert substance diluent [1 x 3.15 mL syringe], 1 pack (<i>Humatrope</i>)
10487Y	SOMATROPIN , somatropin 36 international units (12 mg) injection [1 x 12 mg cartridge] (& inert substance diluent [1 x 3.15 mL syringe], 1 pack (<i>Humatrope</i>)
10476J	SOMATROPIN , somatropin 72 international units (24 mg) injection [1 x 24 mg cartridge] (& inert substance diluent [1 x 3.15 mL syringe], 1 pack (<i>Humatrope</i>)
10502R	SOMATROPIN , somatropin 72 international units (24 mg) injection [1 x 24 mg cartridge] (& inert substance diluent [1 x 3.15 mL syringe], 1 pack (<i>Humatrope</i>)
10435F	SOMATROPIN , SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1 (<i>Genotropin GoQuick</i>)
10443P	SOMATROPIN , SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1 (<i>Genotropin GoQuick</i>)
10426R	SOMATROPIN , SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1 (<i>Genotropin GoQuick</i>)
10431B	SOMATROPIN , SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1 (<i>Genotropin GoQuick</i>)
10427T	SOMATROPIN , somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Omnitrope</i>)
10432C	SOMATROPIN , somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin FlexPro</i>)
10437H	SOMATROPIN , somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin SimpleXx</i>)
10467X	SOMATROPIN , somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin FlexPro</i>)
10469B	SOMATROPIN , somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin SimpleXx</i>)
10484T	SOMATROPIN , somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Omnitrope</i>)
10458K	SOMATROPIN , somatropin 18 international units (6 mg/1.03 mL) injection, 1 x 1.03 mL cartridge (<i>Saizen</i>)
10462P	SOMATROPIN , somatropin 18 international units (6 mg/1.03 mL) injection, 1 x 1.03 mL cartridge (<i>Saizen</i>)
10438J	SOMATROPIN , somatropin 30 international units (10 mg/2 mL) injection, 1 x 2 mL cartridge (<i>NutropinAq</i>)
10439K	SOMATROPIN , somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin SimpleXx</i>)
10441M	SOMATROPIN , somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Omnitrope</i>)
10448X	SOMATROPIN , somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin SimpleXx</i>)
10451C	SOMATROPIN , somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin FlexPro</i>)
10478L	SOMATROPIN , somatropin 30 international units (10 mg/2 mL) injection, 1 x 2 mL cartridge (<i>NutropinAq</i>)
10481P	SOMATROPIN , somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Omnitrope</i>)
10496K	SOMATROPIN , somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin FlexPro</i>)
10483R	SOMATROPIN , somatropin 36 international units (12 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Saizen</i>)
10495J	SOMATROPIN , somatropin 36 international units (12 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Saizen</i>)

10446T	SOMATROPIN , somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Omnitrope Surepal 15</i>)
10449Y	SOMATROPIN , somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin FlexPro</i>)
10468Y	SOMATROPIN , somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin SimpleXx</i>)
10470C	SOMATROPIN , somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin SimpleXx</i>)
10485W	SOMATROPIN , somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Omnitrope Surepal 15</i>)
10489C	SOMATROPIN , somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin FlexPro</i>)
10490D	SOMATROPIN , somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Omnitrope Surepal 15</i>)
10442N	SOMATROPIN , somatropin 60 international units (20 mg/2.5 mL) injection, 1 x 2.5 mL cartridge (<i>Saizen</i>)
10497L	SOMATROPIN , somatropin 60 international units (20 mg/2.5 mL) injection, 1 x 2.5 mL cartridge (<i>Saizen</i>)

Alterations

Alteration – Item Description

From

6329D **SOMATROPIN**, SOMATROPIN (Recombinant human growth hormone) Injection 8 mg (24 i.u.) vial with 1.37 mL diluent cartridge (with preservative) (for use with one.click auto-injector), 1 (*Saizen 8 mg click.easy*)

To

6329D **SOMATROPIN**, SOMATROPIN (Recombinant human growth hormone) Injection 8 mg (24 i.u.) vial with 1.37 mL diluent cartridge (with preservative) (for use with one.click auto-injector), 1 (*Saizen 8 mg click.easy*)

From

9585L **SOMATROPIN**, SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1 (*Genotropin GoQuick*)

To

9585L **SOMATROPIN**, SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1 (*Genotropin GoQuick*)

From

9586M **SOMATROPIN**, SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1 (*Genotropin GoQuick*)

To

9586M **SOMATROPIN**, SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1 (*Genotropin GoQuick*)

Alteration – Restriction

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

3388H	SOMATROPIN, somatropin 60 international units (20 mg/2.5 mL) injection, 1 x 2.5 mL cartridge (<i>Saizen</i>)
5818F	SOMATROPIN, somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin FlexPro</i>)
5819G	SOMATROPIN, somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin FlexPro</i>)
5820H	SOMATROPIN, somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin FlexPro</i>)
5822K	SOMATROPIN, somatropin 18 international units (6 mg/1.03 mL) injection, 1 x 1.03 mL cartridge (<i>Saizen</i>)
5824M	SOMATROPIN, somatropin 36 international units (12 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Saizen</i>)
6169Q	SOMATROPIN, somatropin 18 international units (6 mg) injection [1 x 6 mg cartridge] (&) inert substance diluent [1 x 3.15 mL syringe], 1 pack (<i>Humatrope</i>)
6170R	SOMATROPIN, somatropin 36 international units (12 mg) injection [1 x 12 mg cartridge] (&) inert substance diluent [1 x 3.15 mL syringe], 1 pack (<i>Humatrope</i>)
6266T	SOMATROPIN, somatropin 12 international units (4 mg) injection [1 x 4 mg vial] (&) inert substance diluent [1 vial], 1 pack (<i>Zomacton</i>)

6295H	SOMATROPIN, somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (Norditropin SimpleXx)
6296J	SOMATROPIN, somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (Norditropin SimpleXx)
6297K	SOMATROPIN, somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (Norditropin SimpleXx)
6310D	SOMATROPIN, somatropin 30 international units (10 mg) injection [1 x 10 mg vial] (&) inert substance diluent [1 x 1 mL syringe], 1 pack (Zomacton)
6311E	SOMATROPIN, somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (Omnitrope)
6312F	SOMATROPIN, somatropin 36 international units (12 mg) injection [1 x 12 mg cartridge] (&) inert substance diluent [1 x 1 mL cartridge], 1 pack (Genotropin)
6313G	SOMATROPIN, somatropin 2.4 international units (800 microgram) injection [7 x 800 microgram syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)
6314H	SOMATROPIN, somatropin 3 international units (1 mg) injection [7 x 1 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)
6315J	SOMATROPIN, somatropin 3.6 international units (1.2 mg) injection [7 x 1.2 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)
6316K	SOMATROPIN, somatropin 4.2 international units (1.4 mg) injection [7 x 1.4 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)
6317L	SOMATROPIN, somatropin 4.8 international units (1.6 mg) injection [7 x 1.6 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)
6318M	SOMATROPIN, somatropin 5.4 international units (1.8 mg) injection [7 x 1.8 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)
6319N	SOMATROPIN, somatropin 6 international units (2 mg) injection [7 x 2 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)
6329D	SOMATROPIN, SOMATROPIN (Recombinant human growth hormone) Injection 8 mg (24 i.u.) vial with 1.37 mL diluent cartridge (with preservative) (for use with one.click auto-injector), 1 (Saizen 8 mg click.easy)
6345Y	SOMATROPIN, somatropin 72 international units (24 mg) injection [1 x 24 mg cartridge] (&) inert substance diluent [1 x 3.15 mL syringe], 1 pack (Humatrope)
6476W	SOMATROPIN, somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (Omnitrope)
9585L	SOMATROPIN, SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1 (Genotropin GoQuick)
9586M	SOMATROPIN, SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1 (Genotropin GoQuick)
9604L	SOMATROPIN, somatropin 30 international units (10 mg/2 mL) injection, 1 x 2 mL cartridge (NutropinAq)
9628R	SOMATROPIN, somatropin 1.8 international units (600 microgram) injection [7 x 600 microgram syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (Genotropin MiniQuick)

Alteration – Restriction Level

		<i>From</i>	<i>To</i>
3388H	SOMATROPIN , somatropin 60 international units (20 mg/2.5 mL) injection, 1 x 2.5 mL cartridge (<i>Saizen</i>)	restricted	authority-required
5818F	SOMATROPIN , somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin FlexPro</i>)	restricted	authority-required
5819G	SOMATROPIN , somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin FlexPro</i>)	restricted	authority-required
5820H	SOMATROPIN , somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin FlexPro</i>)	restricted	authority-required
5822K	SOMATROPIN , somatropin 18 international units (6 mg/1.03 mL) injection, 1 x 1.03 mL cartridge (<i>Saizen</i>)	restricted	authority-required
5824M	SOMATROPIN , somatropin 36 international units (12 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Saizen</i>)	restricted	authority-required
6169Q	SOMATROPIN , somatropin 18 international units (6 mg) injection [1 x 6 mg cartridge] (&) inert substance diluent [1 x 3.15 mL syringe], 1 pack (<i>Humatrope</i>)	restricted	authority-required

6170R	SOMATROPIN , somatropin 36 international units (12 mg) injection [1 x 12 mg cartridge] (&) inert substance diluent [1 x 3.15 mL syringe], 1 pack (<i>Humatrope</i>)	restricted	authority-required
6266T	SOMATROPIN , somatropin 12 international units (4 mg) injection [1 x 4 mg vial] (&) inert substance diluent [1 vial], 1 pack (<i>Zomacton</i>)	restricted	authority-required
6295H	SOMATROPIN , somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin SimpleXx</i>)	restricted	authority-required
6296J	SOMATROPIN , somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin SimpleXx</i>)	restricted	authority-required
6297K	SOMATROPIN , somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin SimpleXx</i>)	restricted	authority-required
6310D	SOMATROPIN , somatropin 30 international units (10 mg) injection [1 x 10 mg vial] (&) inert substance diluent [1 x 1 mL syringe], 1 pack (<i>Zomacton</i>)	restricted	authority-required
6311E	SOMATROPIN , somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Omnitrope</i>)	restricted	authority-required
6312F	SOMATROPIN , somatropin 36 international units (12 mg) injection [1 x 12 mg cartridge] (&) inert substance diluent [1 x 1 mL cartridge], 1 pack (<i>Genotropin</i>)	restricted	authority-required
6313G	SOMATROPIN , somatropin 2.4 international units (800 microgram) injection [7 x 800 microgram syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)	restricted	authority-required
6314H	SOMATROPIN , somatropin 3 international units (1 mg) injection [7 x 1 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)	restricted	authority-required
6315J	SOMATROPIN , somatropin 3.6 international units (1.2 mg) injection [7 x 1.2 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)	restricted	authority-required
6316K	SOMATROPIN , somatropin 4.2 international units (1.4 mg) injection [7 x 1.4 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)	restricted	authority-required
6317L	SOMATROPIN , somatropin 4.8 international units (1.6 mg) injection [7 x 1.6 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)	restricted	authority-required
6318M	SOMATROPIN , somatropin 5.4 international units (1.8 mg) injection [7 x 1.8 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)	restricted	authority-required
6319N	SOMATROPIN , somatropin 6 international units (2 mg) injection [7 x 2 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)	restricted	authority-required
6329D	SOMATROPIN , SOMATROPIN (Recombinant human growth hormone) Injection 8 mg (24 i.u.) vial with 1.37 mL diluent cartridge (with preservative) (for use with one.click auto-injector), 1 (<i>Saizen 8 mg click.easy</i>)	restricted	authority-required
6345Y	SOMATROPIN , somatropin 72 international units (24 mg) injection [1 x 24 mg cartridge] (&) inert substance diluent [1 x 3.15 mL syringe], 1 pack (<i>Humatrope</i>)	restricted	authority-required
6476W	SOMATROPIN , somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Omnitrope</i>)	restricted	authority-required
9585L	SOMATROPIN , SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1 (<i>Genotropin GoQuick</i>)	restricted	authority-required
9586M	SOMATROPIN , SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1 (<i>Genotropin GoQuick</i>)	restricted	authority-required
9604L	SOMATROPIN , somatropin 30 international units (10 mg/2 mL) injection, 1 x 2 mL cartridge (<i>NutropinAq</i>)	restricted	authority-required
9628R	SOMATROPIN , somatropin 1.8 international units (600 microgram) injection [7 x 600 microgram syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)	restricted	authority-required
Alteration – Number of Repeats			
		<i>From</i>	<i>To</i>
3388H	SOMATROPIN , somatropin 60 international units (20 mg/2.5 mL) injection, 1 x 2.5 mL cartridge (<i>Saizen</i>)	0	1
5818F	SOMATROPIN , somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin FlexPro</i>)	0	1

5819G	SOMATROPIN , somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin FlexPro</i>)	0	1
5820H	SOMATROPIN , somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin FlexPro</i>)	0	1
5822K	SOMATROPIN , somatropin 18 international units (6 mg/1.03 mL) injection, 1 x 1.03 mL cartridge (<i>Saizen</i>)	0	1
5824M	SOMATROPIN , somatropin 36 international units (12 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Saizen</i>)	0	1
6169Q	SOMATROPIN , somatropin 18 international units (6 mg) injection [1 x 6 mg cartridge] (& inert substance diluent [1 x 3.15 mL syringe], 1 pack (<i>Humatrope</i>)	0	1
6170R	SOMATROPIN , somatropin 36 international units (12 mg) injection [1 x 12 mg cartridge] (& inert substance diluent [1 x 3.15 mL syringe], 1 pack (<i>Humatrope</i>)	0	1
6266T	SOMATROPIN , somatropin 12 international units (4 mg) injection [1 x 4 mg vial] (& inert substance diluent [1 vial], 1 pack (<i>Zomacton</i>)	0	1
6295H	SOMATROPIN , somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin SimpleXx</i>)	0	1
6296J	SOMATROPIN , somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin SimpleXx</i>)	0	1
6297K	SOMATROPIN , somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Norditropin SimpleXx</i>)	0	1
6310D	SOMATROPIN , somatropin 30 international units (10 mg) injection [1 x 10 mg vial] (& inert substance diluent [1 x 1 mL syringe], 1 pack (<i>Zomacton</i>)	0	1
6311E	SOMATROPIN , somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Omnitrope</i>)	0	1
6312F	SOMATROPIN , somatropin 36 international units (12 mg) injection [1 x 12 mg cartridge] (& inert substance diluent [1 x 1 mL cartridge], 1 pack (<i>Genotropin</i>)	0	1
6313G	SOMATROPIN , somatropin 2.4 international units (800 microgram) injection [7 x 800 microgram syringes] (& inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)	0	1
6314H	SOMATROPIN , somatropin 3 international units (1 mg) injection [7 x 1 mg syringes] (& inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)	0	1
6315J	SOMATROPIN , somatropin 3.6 international units (1.2 mg) injection [7 x 1.2 mg syringes] (& inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)	0	1
6316K	SOMATROPIN , somatropin 4.2 international units (1.4 mg) injection [7 x 1.4 mg syringes] (& inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)	0	1
6317L	SOMATROPIN , somatropin 4.8 international units (1.6 mg) injection [7 x 1.6 mg syringes] (& inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)	0	1
6318M	SOMATROPIN , somatropin 5.4 international units (1.8 mg) injection [7 x 1.8 mg syringes] (& inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)	0	1
6319N	SOMATROPIN , somatropin 6 international units (2 mg) injection [7 x 2 mg syringes] (& inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)	0	1
6329D	SOMATROPIN , SOMATROPIN (Recombinant human growth hormone) Injection 8 mg (24 i.u.) vial with 1.37 mL diluent cartridge (with preservative) (for use with one.click auto-injector), 1 (<i>Saizen 8 mg click.easy</i>)	0	1
6345Y	SOMATROPIN , somatropin 72 international units (24 mg) injection [1 x 24 mg cartridge] (& inert substance diluent [1 x 3.15 mL syringe], 1 pack (<i>Humatrope</i>)	0	1
6476W	SOMATROPIN , somatropin 15 international units (5 mg/1.5 mL) injection, 1 x 1.5 mL cartridge (<i>Omnitrope</i>)	0	1
9585L	SOMATROPIN , SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1 (<i>Genotropin GoQuick</i>)	0	1
9586M	SOMATROPIN , SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1 (<i>Genotropin GoQuick</i>)	0	1
9604L	SOMATROPIN , somatropin 30 international units (10 mg/2 mL) injection, 1 x 2 mL cartridge (<i>NutropinAq</i>)	0	1

9628R	SOMATROPIN , somatropin 1.8 international units (600 microgram) injection [7 x 600 microgram syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack (<i>Genotropin MiniQuick</i>)	0	1

IVF Program

Additions

Addition – Item

10491E	FOLLITROPIN ALFA + LUTROPIN ALFA , follitropin alfa 150 units + lutropin alfa 75 units [1 vial] (&) inert substance diluent [1 vial], 1 pack (<i>Pergoveris</i>)
10465T	LUTROPIN ALFA , lutropin alfa 75 international units injection [1 x 75 international units vial] (&) inert substance diluent [1 x 1 mL vial], 1 pack (<i>Luveris</i>)

Repatriation Pharmaceutical Benefits

Alterations

Alteration – Restriction

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

4082W	CALCIUM, CALCIUM Tablet 600 mg (as carbonate), 120 (CAL-600)
4094L	CALCIUM, CALCIUM Tablet (chewable) 500 mg (as carbonate), 60 (Cal-500, Cal-Sup)
4142B	CALCIUM, CALCIUM Tablet 600 mg (as carbonate), 120 (CAL-600)
4333C	CALCIUM, CALCIUM Tablet (chewable) 500 mg (as carbonate), 60 (Cal-500, Cal-Sup)
4046Y	DICLOFENAC, diclofenac sodium 3% gel, 25 g (Solaraze 3% Gel)
4591P	GABAPENTIN, gabapentin 100 mg capsule, 100 (APO-Gabapentin, Gabapentin Aspen 100, Neurontin, Nupentin 100)
4592Q	GABAPENTIN, gabapentin 300 mg capsule, 100 (Gabapentin 300, Gabapentin Aspen 300, Gantin, GenRx Gabapentin, Neurontin, Nupentin 300)
4593R	GABAPENTIN, gabapentin 400 mg capsule, 100 (Gabapentin 400, Gabapentin Aspen 400, Gantin, GenRx Gabapentin, Neurontin, Nupentin 400)
4594T	GABAPENTIN, gabapentin 600 mg tablet, 100 (Gabapentin Aspen 600, GenRx Gabapentin, Neurontin, Nupentin Tabs)
4595W	GABAPENTIN, gabapentin 800 mg tablet, 100 (Gabapentin Aspen 800, Gantin, GenRx Gabapentin, Neurontin, Nupentin Tabs)
4559Y	IMIQUIMOD, imiquimod 5% cream, 12 x 250 mg sachets (APO-Imiquimod, Aldara, Aldiq)
4321K	MAGNESIUM ASPARTATE DIHYDRATE, magnesium aspartate dihydrate 500 mg (equivalent to 37.4 mg of magnesium) tablet, 50 (Mag-Sup, Magmin)
4570M	ORLISTAT, orlistat 120 mg capsule, 84 (Xenical)

General Pharmaceutical Benefits

■ ACAMPROSATE

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 (STREAMLINED)

5366

Alcohol dependence

Clinical criteria:

The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence.

acamprosate calcium 333 mg tablet: enteric, 180 tablets

8357W



Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	1	..	156.02	37.70	Campral [AF]

■ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, secukinumab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
- (iii) patients who wish to recommence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab, etanercept and secukinumab, 22 weeks of treatment in the case of infliximab and 28

weeks of treatment in the case of ustekinumab.

Grandfather patients (secukinumab only).

Applications for patients who commenced treatment with secukinumab for chronic plaque psoriasis prior to 1 September 2015 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

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

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

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

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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 Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, **AND**

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**

Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

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

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

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

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**

Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

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

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

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**

The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

9428F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1763.56	37.70	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9427E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1763.56	37.70	Humira [VE]

■ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, secukinumab and ustekinumab, for adult patients with severe chronic plaque

psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
- (iii) patients who wish to recommence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab, etanercept and secukinumab, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

Grandfather patients (secukinumab only).

Applications for patients who commenced treatment with secukinumab for chronic plaque psoriasis prior to 1 September 2015 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

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

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

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

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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 Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**

Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

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

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, **AND**

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**

Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

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

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment

Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**

Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

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

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to

determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**

Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

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

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment

Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment) restriction to complete 16 weeks treatment, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges

9426D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	1763.56	37.70	Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9425C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	1763.56	37.70	Humira [VE]

■ AMANTADINE

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

Parkinson disease

Clinical criteria:

The condition must not be drug induced.

amantadine hydrochloride 100 mg capsule, 100

3016R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	43.80	37.70	Symmetrel 100 [NV]

■ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN

Restricted benefit

Proven glutaric aciduria type 1

amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 30 x 24 g sachets

9438R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*2113.41	37.70	GA gel [VF]

amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 30 x 25 g sachets

5484P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*3154.93	37.70	GA express 15 [VF]

amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 400 g

2650L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*763.33	37.70	GA1 Anamix infant [SB]

amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 500 g

10466W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	9	5	..	*3079.71	37.70	XLYS, LOW TRY Maxamum [SB]

amino acid formula with vitamins and minerals without lysine and low in tryptophan oral liquid: powder for, 500 g

2646G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*1773.89	37.70	XLYS, LOW TRY Maxamaid [SB]

■ BISOPROLOL

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

Moderate to severe heart failure

Clinical criteria:

Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

bisoprolol fumarate 10 mg tablet, 28

8606Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	33.96	35.13	^a APO-Bisoprolol [TX] ^a Bicard 10 [QA] ^a Bisoprolol AN [EA] ^a Bisoprolol Sandoz [SZ] ^a Chem mart Bisoprolol [CH]	^a Beprol 10 [DO] ^a Biso 10 [GN] ^a Bisoprolol generichealth [GQ] ^a Bispro 10 [AF] ^a Terry White Chemists Bisoprolol [TW]
			^B 3.01	36.97	35.13	^a Bicolor [AL]	

bisoprolol fumarate 2.5 mg tablet, 28

8604W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	25.48	26.65	^a APO-Bisoprolol [TX] ^a Bicard 2.5 [QA] ^a Bisoprolol AN [EA] ^a Bisoprolol Sandoz [SZ] ^a Chem mart Bisoprolol [CH]	^a Beprol 2.5 [DO] ^a Biso 2.5 [GN] ^a Bisoprolol generichealth [GQ] ^a Bispro 2.5 [AF] ^a Terry White Chemists Bisoprolol [TW]
			^B 3.01	28.49	26.65	^a Bicolor [AL]	

bisoprolol fumarate 5 mg tablet, 28

8605X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	29.25	30.42	^a APO-Bisoprolol [TX] ^a Bicard 5 [QA] ^a Bisoprolol AN [EA] ^a Bisoprolol Sandoz [SZ] ^a Chem mart Bisoprolol [CH]	^a Beprol 5 [DO] ^a Biso 5 [GN] ^a Bisoprolol generichealth [GQ] ^a Bispro 5 [AF] ^a Terry White Chemists Bisoprolol [TW]
			^B 3.01	32.26	30.42	^a Bicolor [AL]	

■ BROMOCRIPTINE

Restricted benefit

Prevention of the onset of lactation

Clinical criteria:

The treatment must occur in the puerperium, **AND**

The treatment must be for medical reasons.

bromocriptine 2.5 mg tablet, 30

1444B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	21.29	22.46	^a Kripton 2.5 [AF]	^a Parlodel [NV]

■ BROMOCRIPTINE

Caution Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Note For item codes 1443Y and 1559C, pharmaceutical benefits that have the form tablet 2.5 mg (base) are equivalent for the purposes of substitution.

Restricted benefit

Acromegaly

Restricted benefit

Parkinson disease

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

Patient must be one in whom surgery is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

Patient must have had surgery for this condition with incomplete resolution.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

Patient must be one in whom radiotherapy is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

Patient must have had radiotherapy for this condition with incomplete resolution.

bromocriptine 2.5 mg tablet, 30

1443Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*32.17	33.34	^a Parlodel [NV]

bromocriptine 2.5 mg tablet, 60

1559C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	32.16	33.33	^a Kripton 2.5 [AF]

■ CABERGOLINE

Restricted benefit

Prevention of the onset of lactation

Clinical criteria:

The treatment must occur in the puerperium, **AND**

The treatment must be for medical reasons.

cabergoline 500 microgram tablet, 2

8115D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	23.78	24.95	^a Dostan [GN]	^a Dostinex [PF]

■ CABERGOLINE

Caution Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

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

Parkinson disease

cabergoline 1 mg tablet, 30

8393R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	58.93	37.70	^a Cabaser [PF]	^a Cobasol [GN]

cabergoline 2 mg tablet, 30

8394T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	75.44	37.70	^a Cabaser [PF]	^a Cobasol [GN]

■ CABERGOLINE**Restricted benefit**

Pathological hyperprolactinaemia

Clinical criteria:

Patient must be one in whom surgery is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

Patient must have had surgery for this condition with incomplete resolution.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

Patient must be one in whom radiotherapy is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

Patient must have had radiotherapy for this condition with incomplete resolution.

cabergoline 500 microgram tablet, 8

8114C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	63.88	37.70	^a Dostan [GN]	^a Dostinex [PF]

■ CALCITRIOL**Authority required (STREAMLINED)****5401**

Hypocalcaemia

Clinical criteria:

The condition must be due to renal disease.

Authority required (STREAMLINED)**5255**

Hypoparathyroidism

Authority required (STREAMLINED)**5089**

Hypophosphataemic rickets

Authority required (STREAMLINED)**5114**

Vitamin D-resistant rickets

Authority required (STREAMLINED)**5402**

Established osteoporosis

Clinical criteria:

Patient must have fracture due to minimal trauma.

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.

calcitriol 0.25 microgram capsule, 100

2502Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	3	..	31.17	32.34	^a Calciprox [ER] ^a Calcitriol-GA [UA] ^a GenRx Calcitriol [GX] ^a Rocaltrol [RO]	^a Calcitriol AN [EA] ^a Calcitriol Sandoz [SZ] ^a Kosteo [QA] ^a Sical [AF]

■ CARVEDILOL**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

Moderate to severe heart failure

Clinical criteria:

Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

Restricted benefit

Patients receiving this drug as a pharmaceutical benefit prior to 1 August 2002

carvedilol 12.5 mg tablet, 60

8257N

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	26.74	27.91	^a APO-Carvedilol [TX] ^a Carvedilol generichealth [GQ] ^a Chem mart Carvedilol 12.5 mg [CH] ^a Dilatrend 12.5 [RO] ^a Terry White Chemists Carvedilol 12.5 mg [TW] ^a Volirop 12.5 [DO]	^a Carvedilol AN [EA] ^a Carvedilol Sandoz [SZ] ^a Dicarz [AF] ^a GN-Carvedilol [GN] ^a Vedilol 12.5 [QA]

carvedilol 25 mg tablet, 60

8258P

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	30.83	32.00	^a APO-Carvedilol [TX] ^a Carvedilol generichealth [GQ] ^a Chem mart Carvedilol 25 mg [CH] ^a Dilatrend 25 [RO] ^a Terry White Chemists Carvedilol 25 mg [TW] ^a Volirop 25 [DO]	^a Carvedilol AN [EA] ^a Carvedilol Sandoz [SZ] ^a Dicarz [AF] ^a GN-Carvedilol [GN] ^a Vedilol 25 [QA]

carvedilol 3.125 mg tablet, 30

8255L

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	13.18	14.35	^a APO-Carvedilol [TX] ^a Chem mart Carvedilol 3.125 mg [CH] ^a GN-Carvedilol [GN] ^a Vedilol 3.125 [QA]	^a Carvedilol AN [EA] ^a Dilatrend 3.125 [RO] ^a Terry White Chemists Carvedilol 3.125 mg [TW] ^a Volirop 3.125 [DO]

carvedilol 6.25 mg tablet, 60

8256M

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	23.47	24.64	^a APO-Carvedilol [TX] ^a Carvedilol generichealth [GQ] ^a Chem mart Carvedilol 6.25 mg [CH] ^a Dilatrend 6.25 [RO] ^a Terry White Chemists Carvedilol 6.25 mg [TW] ^a Volirop 6.25 [DO]	^a Carvedilol AN [EA] ^a Carvedilol Sandoz [SZ] ^a Dicarz [AF] ^a GN-Carvedilol [GN] ^a Vedilol 6.25 [QA]

■ CITALOPRAM

Restricted benefit

Major depressive disorders

citalopram 10 mg tablet, 28

8702B

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	11.84	13.01	^a Celapram [AF] ^a Citalopram-GA [GN]	^a Citalopram Actavis [UA] ^a Talam [QA]

citalopram 20 mg tablet, 28

8220P

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	..	12.57	13.74	^a APO-Citalopram [TX] ^a Celapram [AF] ^a Chem mart Citalopram [CH] ^a Citalopram Actavis [VN] ^a Citalopram-GA [GN] ^a Citalopram Sandoz [SZ]	^a Auro-Citalopram 20 [DO] ^a Celica [RA] ^a Ciazil [UA] ^a Citalopram AN [EA] ^a Citalopram generichealth [GQ] ^a Pharmacor Citalo 20 [CR]

					^a Talam [QA]	^a Terry White Chemists Citalopram [TW]
		^B 4.95	17.52	13.74	^a Cipramil [LU]	

citalopram 40 mg tablet, 28

8703C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	14.06	15.23	^a APO-Citalopram [TX] ^a Celapram [AF] ^a Citalopram AN [EA] ^a Citalopram Sandoz [SZ]	^a Auro-Citalopram 40 [DO] ^a Citalopram Actavis [VN] ^a Citalopram-GA [GN] ^a Talam [QA]

■ DESMOPRESSIN

Authority required (STREAMLINED)

5266

Cranial diabetes insipidus

desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations

8711L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*150.99	37.70	Minirin Nasal Spray [FP]

desmopressin acetate 100 microgram/mL nasal drops, 2.5 mL

2129C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	5	..	*151.13	37.70	Minirin [FP]

desmopressin acetate 200 microgram tablet, 30

8662X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*168.12	37.70	Minirin [FP]

■ DESMOPRESSIN

Note Not to be used in preference to enuresis alarms.

Note Only one application per six months with no more than twice the maximum quantity will be authorised for the tablets.

Authority required (STREAMLINED)

5413

Primary nocturnal enuresis

Clinical criteria:

Patient must be refractory to an enuresis alarm.

Population criteria:

Patient must be 6 years of age or older.

Authority required (STREAMLINED)

5295

Primary nocturnal enuresis

Clinical criteria:

Patient must be one in whom an enuresis alarm is contraindicated.

Population criteria:

Patient must be 6 years of age or older.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

desmopressin acetate 200 microgram tablet, 30

8663Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	62.99	37.70	Minirin [FP]

■ DESMOPRESSIN

Caution Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.

Note Not to be used in preference to enuresis alarms.

Authority required (STREAMLINED)

5342

Primary nocturnal enuresis

Clinical criteria:

Patient must be refractory to an enuresis alarm.

Population criteria:

Patient must be 6 years of age or older.

Authority required (STREAMLINED)

5267

Primary nocturnal enuresis

Clinical criteria:

Patient must be one in whom an enuresis alarm is contraindicated.

Population criteria:

Patient must be 6 years of age or older.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations

8712M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	80.70	37.70	Minirin Nasal Spray [FP]

■ DESMOPRESSIN

Note Not to be used in preference to enuresis alarms.

Note Only one application per six months will be authorised for the wafers. No more than twice the maximum quantity for the 120 micrograms wafers and no applications for increased maximum quantities for the 240 micrograms wafers will be authorised.

Authority required (STREAMLINED)**5412**

Primary nocturnal enuresis

Clinical criteria:

Patient must be refractory to an enuresis alarm.

Population criteria:

Patient must be 6 years of age or older.

Authority required (STREAMLINED)**5226**

Primary nocturnal enuresis

Clinical criteria:

Patient must be one in whom an enuresis alarm is contraindicated.

Population criteria:

Patient must be 6 years of age or older.

The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated

desmopressin 120 microgram wafer: sublingual, 30

9398P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	68.99	37.70	Minirin Melt [FP]

desmopressin 240 microgram wafer: sublingual, 30

8975J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	109.98	37.70	Minirin Melt [FP]

■ DICLOXACILLIN**Restricted benefit**

Serious staphylococcal infection

dicloxacillin 250 mg capsule, 24

5096F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	15.93	17.10	Distaph 250 [AF]

dicloxacillin 500 mg capsule, 24

5097G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	1	..	..	20.06	21.23	Distaph 500 [AF]

■ DICLOXACILLIN**Restricted benefit**

Serious staphylococcal infection

dicloxacillin 250 mg capsule, 24

8121K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	1	..	..	15.93	17.10	Distaph 250 [AF]

dicloxacillin 500 mg capsule, 24

8122L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP MW	1	..	..	20.06	21.23	Distaph 500 [AF]

■ ELETRIPTAN

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.

Restricted benefit

Migraine attack

Clinical criteria:

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

eletriptan 40 mg tablet, 4

5290K

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	26.37	27.54	Relpax [PF]

eletriptan 80 mg tablet, 4

5291L

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	26.37	27.54	Relpax [PF]

■ ENTACAPONE**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

Parkinson disease

Clinical criteria:

The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination, **AND** Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

entacapone 200 mg tablet, 100

8367J

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2	4	..	*270.53	37.70	Comtan [NV]

■ ETANERCEPT**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, secukinumab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iii) patients who wish to recommence treatment following a break in PBS-subsidised therapy with that agent (Initial 2). All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab, etanercept and secukinumab, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

Grandfather patients (secukinumab only).

Applications for patients who commenced treatment with secukinumab for chronic plaque psoriasis prior to 1 September 2015 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

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

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

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

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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 Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, **AND**

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**

Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

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

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

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

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**

Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment

course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course.

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

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

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**

The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

9462B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1763.57	37.70	Enbrel [PF]

ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

9431J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1763.57	37.70	Enbrel [PF]

etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

9429G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1763.55	37.70	Enbrel [PF]

■ ETANERCEPT**Note** TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, secukinumab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
- (iii) patients who wish to recommence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab, etanercept and secukinumab, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

Grandfather patients (secukinumab only).

Applications for patients who commenced treatment with secukinumab for chronic plaque psoriasis prior to 1 September 2015 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

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

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

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

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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 Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**

Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

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

-
- (a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
(iii) the signed patient and prescriber acknowledgements.
- Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)
- Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.
- Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.
- 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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001
-

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, **AND**

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**

Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

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

- (a) a completed authority prescription form; and
(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

- Note** A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to

respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**

Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

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

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

- (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
- (iii) the signed patient and prescriber acknowledgements.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**

Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

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

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment) restriction to complete 16 weeks treatment, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4, 1

9461Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1763.57	37.70	Enbrel [PF]

ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4, 1

9091L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1763.57	37.70	Enbrel [PF]

etanercept 25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

9037P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	3	..	*1763.55	37.70	Enbrel [PF]

▪ FEBUXOSTAT

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

Chronic gout

Clinical criteria:

The condition must be either chronic gouty arthritis or chronic tophaceous gout, **AND**

Patient must have a medical contraindication to allopurinol; OR

Patient must have a documented history of allopurinol hypersensitivity syndrome; OR
 Patient must have an intolerance to allopurinol necessitating permanent treatment discontinuation.

febuxostat 80mg tablet, 28

10445R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	50.27	37.70	Adenuric [FK]

■ 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	..	14.90	16.07	^a Flubiclox [GN] ^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	..	..	14.90	16.07	^a Flubiclox [GN] ^a Hospira Pty Limited [HH]	^a Flucil [AS]

flucloxacillin 500 mg injection, 5 x 500 mg vials

1524F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	13.28	14.45	^a Flubiclox [GN]	^a Flucil [AS]

flucloxacillin 500 mg injection, 5 x 500 mg vials

5094D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	13.28	14.45	^a Flubiclox [GN]	^a Flucil [AS]

■ 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.

Restricted benefit

Serious staphylococcal infection

flucloxacillin 250 mg capsule, 24

1526H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	..	..	14.57	15.74	^a APO-Flucloxacillin [TX] ^a Staphylex 250 [AF]	^a Flopen [AS]

flucloxacillin 500 mg capsule, 24

1527J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP MW	1	..	..	19.11	20.28	^a APO-Flucloxacillin [TX] ^a Staphylex 500 [AF]	^a Flopen [AS]

■ 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.

Restricted benefit

Serious staphylococcal infection

flucloxacillin 125 mg/5 mL oral liquid: powder for, 100 mL

5257Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	‡1	..	..	#19.20	20.73	Flucil [LN]

flucloxacillin 250 mg capsule, 24

5090X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	14.57	15.74	^a APO-Flucloxacillin [TX] ^a Staphylex 250 [AF]	^a Flopen [AS]

flucloxacillin 250 mg/5 mL oral liquid: powder for, 100 mL

5258R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	‡1	..	..	#22.27	23.80	Flucil [LN]

flucloxacillin 500 mg capsule, 24

5091Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
DP	1	..	..	19.11	20.28	^a APO-Flucloxacillin [TX] ^a Staphylex 500 [AF]	^a Flopen [AS]

■ 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.

Restricted benefit

Serious staphylococcal infection

flucloxacillin 125 mg/5 mL oral liquid: powder for, 100 mL

9149M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	#1	..	..	#19.20	20.73	Flucil [LN]

flucloxacillin 250 mg/5 mL oral liquid: powder for, 100 mL

9150N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	#1	..	..	#22.27	23.80	Flucil [LN]

■ GABAPENTIN

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)

4928

Partial epileptic seizures

Clinical criteria:

The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

gabapentin 100 mg capsule, 100

8505P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	15.80	16.97	^a APO-Gabapentin [TX] ^a Gabapentin Aspen 100 [FM] ^a Nupentin 100 [AF]	^a Gabacor [CR] ^a Neurontin [PF]

gabapentin 300 mg capsule, 100

1834M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	28.39	29.56	^a Gabacor [CR] ^a Gabapentin-GA [UA] ^a Gabapentin Sandoz [SZ] ^a GenRx Gabapentin [GX] ^a Nupentin 300 [AF]	^a Gabapentin Aspen 300 [FM] ^a Gabapentin GH [GQ] ^a Gantin [GN] ^a Neurontin [PF]

gabapentin 400 mg capsule, 100

1835N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	34.92	36.09	^a Gabacor [CR] ^a Gabapentin GH [GQ] ^a Gantin [GN] ^a Neurontin [PF]	^a Gabapentin Aspen 400 [FM] ^a Gabapentin Sandoz [SZ] ^a GenRx Gabapentin [GX] ^a Nupentin 400 [AF]

gabapentin 600 mg tablet, 100

8559L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	49.32	37.70	^a Gabapentin AN [EA] ^a Gabaran [RA] ^a Neurontin [PF] ^a Pharmacor Gabapentin 600 [CR]	^a Gabapentin Aspen 600 [FM] ^a GenRx Gabapentin [GX] ^a Nupentin Tabs [AF]

gabapentin 800 mg tablet, 100

8389M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	62.28	37.70	^a Gabapentin AN [EA] ^a Gabaran [RA] ^a GenRx Gabapentin [GX] ^a Nupentin Tabs [AF]	^a Gabapentin Aspen 800 [FM] ^a Gantin [GN] ^a Neurontin [PF] ^a Pharmacor Gabapentin 800 [CR]

■ INSULIN DETEMIR

Restricted benefit

Type 1 diabetes

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

9040T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	5	1	..	*426.73	37.70	Levemir FlexPen [NF]	Levemir Penfill [NO]

■ ISOTRETINOIN

Caution This drug causes birth defects.

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

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

Authority required (STREAMLINED)

5224

Severe cystic acne

Clinical criteria:

The condition must be unresponsive to other therapy.

isotretinoin 10 mg capsule, 60

2591J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	42.45	37.70	^a APO-Isotretinoin [TX] ^a Isotretinoin AN [EA] ^a Oratane [GN] ^a Rocta 10 [QA]	^a Dermatane [ER] ^a Isotretinoin SCP 10 [CR] ^a Roaccutane [RO]

isotretinoin 20 mg capsule, 60

2592K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	60.33	37.70	^a APO-Isotretinoin [TX] ^a Isotretinoin AN [EA] ^a Oratane [GN] ^a Rocta 20 [QA]	^a Dermatane [ER] ^a Isotretinoin SCP 20 [CR] ^a Roaccutane [RO]

isotretinoin 40 mg capsule, 30

2549E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	55.47	37.70	^a Dermatane [ER]	^a Oratane [GN]

■ LAMOTRIGINE

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)

5138

Epileptic seizures

Clinical criteria:

The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

lamotrigine 100 mg tablet, 56

2850B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	34.38	35.55	^a APO-Lamotrigine [TX] ^a Lamidus [RA] ^a Lamotrigine AN [EA] ^a Lamotrigine-GA [GN] ^a Lamotrigine Sandoz [SZ] ^a Logem [AL] ^a Seaze 100 [QA]	^a GenRx Lamotrigine [GX] ^a Lamogine [AF] ^a Lamotrigine Aspen 100 [FM] ^a Lamotrigine generichealth [GQ] ^a Lamotrust 100 [CR] ^a Reedos 100 [DO] ^a Torlemo DT 100 [UA]
			^b 2.32	36.70	35.55	^a Lamictal [AS]	

lamotrigine 200 mg tablet, 56

2851C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	50.68	37.70	^a APO-Lamotrigine [TX] ^a Lamidus [RA] ^a Lamotrigine AN [EA] ^a Lamotrigine-GA [GN] ^a Lamotrigine Sandoz [SZ] ^a Logem [AL] ^a Seaze 200 [QA]	^a GenRx Lamotrigine [GX] ^a Lamogine [AF] ^a Lamotrigine Aspen 200 [FM] ^a Lamotrigine generichealth [GQ] ^a Lamotrust 200 [CR] ^a Reedos 200 [DO] ^a Torlemo DT 200 [UA]
			^b 2.32	53.00	37.70	^a Lamictal [AS]	

lamotrigine 25 mg tablet, 56

2848X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	19.04	20.21	^a APO-Lamotrigine [TX] ^a Lamidus [RA] ^a Lamotrigine AN [EA] ^a Lamotrigine-GA [GN] ^a Lamotrigine Sandoz [SZ] ^a Logem [AL] ^a Seaze 25 [QA]	^a GenRx Lamotrigine [GX] ^a Lamogine [AF] ^a Lamotrigine Aspen 25 [FM] ^a Lamotrigine generichealth [GQ] ^a Lamotrust 25 [CR] ^a Reedos 25 [DO] ^a Torlemo DT 25 [UA]
			^B 2.51	21.55	20.21	^a Lamictal [AS]	

lamotrigine 5 mg tablet, 56

8063J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	14.29	15.46	^a Lamogine [AF] ^a Seaze 5 [QA]	^a Lamotrigine Aspen 5 [FM]
			^B 1.72	16.01	15.46	^a Lamictal [AS]	

lamotrigine 50 mg tablet, 56

2849Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	24.81	25.98	^a APO-Lamotrigine [TX] ^a Lamidus [RA] ^a Lamotrigine AN [EA] ^a Lamotrigine-GA [GN] ^a Lamotrigine Sandoz [SZ] ^a Logem [AL] ^a Seaze 50 [QA]	^a GenRx Lamotrigine [GX] ^a Lamogine [AF] ^a Lamotrigine Aspen 50 [FM] ^a Lamotrigine generichealth [GQ] ^a Lamotrust 50 [CR] ^a Reedos 50 [DO] ^a Torlemo DT 50 [UA]
			^B 2.22	27.03	25.98	^a Lamictal [AS]	

■ LEVETIRACETAM

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)

4928

Partial epileptic seizures

Clinical criteria:

The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

levetiracetam 1 g tablet, 60

8656N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	73.39	37.70	^a APO-Levetiracetam [TX] ^a Kepcet [GN] ^a Kerron 1000 [DO] ^a Levactam [ER] ^a Levetiracetam AN [EA] ^a Levetiracetam SZ [SZ] ^a Levitaccord [RA] ^a Terry White Chemists Levetiracetam [TW]	^a Chem mart Levetiracetam [CH] ^a Keppra [UC] ^a Kevtam [AF] ^a Levecetam 1000 [RZ] ^a Levetiracetam generichealth [GQ] ^a Levi 1000 [FM] ^a Levitam 1000 [QA]

levetiracetam 250 mg tablet, 60

8654L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	33.10	34.27	^a APO-Levetiracetam [TX] ^a Kepcet [GN] ^a Kerron 250 [DO] ^a Levactam [ER] ^a Levetiracetam AN [EA] ^a Levetiracetam SZ [SZ] ^a Levitaccord [RA] ^a Terry White Chemists Levetiracetam [TW]	^a Chem mart Levetiracetam [CH] ^a Keppra [UC] ^a Kevtam [AF] ^a Levecetam 250 [RZ] ^a Levetiracetam generichealth [GQ] ^a Levi 250 [FM] ^a Levitam 250 [QA]

levetiracetam 500 mg tablet, 60

8655M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	48.21	37.70	^a APO-Levetiracetam [TX] ^a Kepcet [GN] ^a Kerron 500 [DO] ^a Levactam [ER] ^a Levetiracetam AN [EA] ^a Levetiracetam SZ [SZ] ^a Levitaccord [RA] ^a Terry White Chemists Levetiracetam [TW]	^a Chem mart Levetiracetam [CH] ^a Keppra [UC] ^a Kevtam [AF] ^a Levecetam 500 [RZ] ^a Levetiracetam generichealth [GQ] ^a Levi 500 [FM] ^a Levitam 500 [QA]

■ LEVETIRACETAM

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)

5215

Partial epileptic seizures

Clinical criteria:

The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, **AND**

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

levetiracetam 100 mg/mL oral liquid, 300 mL

9169N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	72.78	37.70	^a Keppra [UC] ^a Levetiracetam-AFT [AE]	^a Kerron [DO]

■ LEVODOPA + CARBIDOPA ANHYDROUS

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

Parkinson disease

Clinical criteria:

The condition must be one in which fluctuations in motor function are not adequately controlled by frequent dosing with conventional formulations of levodopa with decarboxylase inhibitor.

levodopa 200 mg + carbidopa anhydrous 50 mg tablet: modified release, 100 tablets

1255C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	66.28	37.70	Sinemet CR [MK]

■ LEVODOPA + CARBIDOPA ANHYDROUS + ENTACAPONE

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

Parkinson disease

Clinical criteria:

Patient must be being treated with levodopa decarboxylase inhibitor combinations, **AND**

Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

Restricted benefit

Parkinson disease

Clinical criteria:

Patient must be stabilised on concomitant treatment with levodopa decarboxylase inhibitor combinations and entacapone.

levodopa 100 mg + carbidopa anhydrous 25 mg + entacapone 200 mg tablet, 100

8798C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	4	..	*332.73	37.70	Stalevo 100/25/200mg [NV]

levodopa 125 mg + carbidopa anhydrous 31.25 mg + entacapone 200 mg tablet, 100

9345W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	4	..	*345.19	37.70	Stalevo 125/31.25/200mg [NV]

levodopa 150 mg + carbidopa anhydrous 37.5 mg + entacapone 200 mg tablet, 100

8799D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	4	..	*363.83	37.70	Stalevo 150/37.5/200mg [NV]

levodopa 200 mg + carbidopa anhydrous 50 mg + entacapone 200 mg tablet, 100

9292C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	4	..	*392.45	37.70	Stalevo 200/50/200mg [NV]

levodopa 50 mg + carbidopa anhydrous 12.5 mg + entacapone 200 mg tablet, 100

8797B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	4	..	*301.65	37.70	Stalevo 50/12.5/200mg [NV]

levodopa 75 mg + carbidopa anhydrous 18.75 mg + entacapone 200 mg tablet, 100

9344T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	4	..	*315.35	37.70	Stalevo 75/18.75/200mg [NV]

■ LEVONORGESTREL**Restricted benefit**

Contraception

Restricted benefit

Idiopathic menorrhagia

Clinical criteria:

The treatment must be in a patient where oral treatments are ineffective.

Restricted benefit

Idiopathic menorrhagia

Clinical criteria:

The treatment must be in a patient where oral treatments are contraindicated.

levonorgestrel 52 mg drug delivery system: intrauterine, 1 system

8633J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	254.38	37.70	Mirena [BN]

■ LISDEXAMFETAMINE**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.**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** Special Pricing Arrangements apply.**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

Attention deficit hyperactivity disorder

Clinical criteria:

Patient must require continuous coverage over 12 hours.

Population criteria:

Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.

lisdexamfetamine dimesilate 30 mg capsule, 30

10486X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	116.33	37.70	Vyvanse [ZI]

lisdexamfetamine dimesilate 50 mg capsule, 30

10474G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	116.33	37.70	Vyvanse [ZI]

lisdexamfetamine dimesilate 70 mg capsule, 30

10492F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	116.33	37.70	Vyvanse [ZI]

■ MAGNESIUM ASPARTATE DIHYDRATE**Authority required**

Hypomagnesaemia

Population criteria:

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

Authority required

Chronic renal disease

Population criteria:

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

magnesium aspartate dihydrate 500 mg (equivalent to 37.4 mg of magnesium) tablet, 50

5146W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	16.75	17.92	MagMin (PBS) [BB]	Mag-Sup [PP]

■ METHYLPREDNISOLONE**methylprednisolone Powder for injection 1 g (as sodium succinate), 1**

5264C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	54.84	37.70	^a Methylpred [AL] ^a Solu-Medrol [PF]	^a Methylprednisolone Alphapharm [AF]

■ METOPROLOL SUCCINATE**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

Moderate to severe heart failure

Clinical criteria:

Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30

8735R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	89.21	37.70	^a Metrol-XL 190 [QA] ^a Toprol-XL 190 [AP]	^a Minax XL [AF]

METOPROLOL SUCCINATE Tablet 23.75 mg (controlled release), 15

8732N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	21.10	22.27	^a Metrol-XL 23.75 [QA] ^a Toprol-XL 23.75 [AP]	^a Minax XL [AF]

METOPROLOL SUCCINATE Tablet 47.5 mg (controlled release), 30

8733P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	60.86	37.70	^a Metrol-XL 47.5 [QA] ^a Toprol-XL 47.5 [AP]	^a Minax XL [AF]

METOPROLOL SUCCINATE Tablet 95 mg (controlled release), 30

8734Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	73.45	37.70	^a Metrol-XL 95 [QA] ^a Toprol-XL 95 [AP]	^a Minax XL [AF]

■ MINOXIDIL**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

Severe refractory hypertension

Clinical criteria:

The treatment must be initiated by a consultant physician.

minoxidil 10 mg tablet, 100

2313R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.37	37.70	Loniten [PF]

■ NAFARELIN**Authority required**

Endometriosis

Treatment Phase: Initial treatment, for up to 6 months

Clinical criteria:

The condition must be visually proven.

Authority required

Endometriosis
Treatment Phase: Subsequent treatment, for up to 6 months

Clinical criteria:

The condition must be visually proven, **AND**

The treatment must not be within 2 years of the end of the previous course of treatment with this drug, **AND**

Patient must have had a recent bone density assessment.

The date of the bone density assessment must be provided.

nafarelin 200 microgram/actuation nasal spray, 60 actuations

2962X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	124.39	37.70	Synarel [PF]

■ **NALTREXONE**

Caution Naltrexone hydrochloride is contraindicated in patients receiving opioid drugs.

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

Alcohol dependence

Clinical criteria:

The treatment must be part of a comprehensive treatment program with the goal of maintaining abstinence.

naltrexone hydrochloride 50 mg tablet, 30

8370M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	127.92	37.70	^a Naltrexone GH [GQ]	^a ReVia [BQ]

■ **NANDROLONE DECANOATE**

Note Monotherapy for the treatment of osteoporosis does not exclude calcium supplementation.

Authority required

Osteoporosis

Clinical criteria:

The treatment must be as monotherapy, **AND**

The treatment must be where other treatment has failed and where specialist advice confirms that this is the only suitable treatment option for the patient.

Specialist advice need only be obtained for the first authority approval.

Authority required

Osteoporosis

Clinical criteria:

The treatment must be as monotherapy, **AND**

The treatment must be where other treatment is not tolerated and where specialist advice confirms that this is the only suitable treatment option for the patient.

Specialist advice need only be obtained for the first authority approval.

Authority required

Osteoporosis

Clinical criteria:

The treatment must be as monotherapy, **AND**

The treatment must be where other treatment is contraindicated and where specialist advice confirms that this is the only suitable treatment option for the patient.

Specialist advice need only be obtained for the first authority approval.

Authority required

Patients receiving this drug as a pharmaceutical benefit prior to 1 February 2004

Authority required

Patients on long-term treatment with corticosteroids

nandrolone decanoate 50 mg/mL injection, 1 x 1 mL syringe

1671Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	7	..	23.27	24.44	Deca-Durabolin [AS]

■ **NEBIVOLOL**

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

Moderate to severe heart failure

Clinical criteria:

Patient must be stabilised on conventional therapy, which must include an ACE inhibitor or Angiotensin II antagonist, if tolerated.

nebivolol 1.25 mg tablet, 28

9316H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*50.13	37.70	Nebilet [FK]

nebivolol 10 mg tablet, 28

9312D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	66.42	37.70	Nebilet [FK]

nebivolol 5 mg tablet, 28

9311C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	59.98	37.70	Nebilet [FK]

■ NICOTINE

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

Nicotine dependence

Clinical criteria:

The treatment must be the sole PBS-subsidised therapy for this condition, **AND**

Patient must have indicated they are ready to cease smoking, **AND**

Patient must have entered a comprehensive support and counselling program, **AND**

Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

Restricted benefit

Nicotine dependence

Clinical criteria:

The treatment must be the sole PBS-subsidised therapy for this condition, **AND**

Patient must have indicated they are ready to cease smoking, **AND**

Patient must be entering a comprehensive support and counselling program during the consultation at which this prescription is written, **AND**

Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

nicotine 14 mg/24 hours patch, 28

5572G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	54.72	37.70	Nicotinell Step 2 [NC]

nicotine 21 mg/24 hours patch, 28

3414Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	54.72	37.70	Nicotinell Step 1 [NC]

nicotine 7 mg/24 hours patch, 28

5573H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	54.72	37.70	Nicotinell Step 3 [NC]

■ NICOTINE

Note Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period.

Benefit is improved if used in conjunction with a comprehensive support and counselling program.

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

Nicotine dependence

Clinical criteria:

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

Population criteria:

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

nicotine 21 mg/24 hours patch, 28

5571F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	54.72	37.70	Nicotinell Step 1 [NC]

■ NICOTINE

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

Nicotine dependence

Clinical criteria:

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

Population criteria:

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

Note Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period. Benefit is improved if used in conjunction with a comprehensive support and counselling program.

Restricted benefit

Nicotine dependence

Clinical criteria:

The treatment must be the sole PBS-subsidised therapy for this condition, **AND**

Patient must have indicated they are ready to cease smoking, **AND**

Patient must have entered a comprehensive support and counselling program, **AND**

Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

Restricted benefit

Nicotine dependence

Clinical criteria:

The treatment must be the sole PBS-subsidised therapy for this condition, **AND**

Patient must have indicated they are ready to cease smoking, **AND**

Patient must be entering a comprehensive support and counselling program during the consultation at which this prescription is written, **AND**

Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

nicotine 21 mg/24 hours patch, 28

5465P

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	2	..	54.72	37.70	Nicabate P [GC]

nicotine 25 mg/16 hours patch, 28

10076H

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	2	..	54.72	37.70	nicorette 16hr Invisipatch [JT]

■ OXCARBAZEPINE

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)

5183

Seizures

Clinical criteria:

Patient must have partial epileptic seizures; OR

Patient must have primary generalised tonic-clonic seizures, **AND**

The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

oxcarbazepine 150 mg tablet, 100

8584T

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	70.28	37.70	Trileptal [NV]

oxcarbazepine 300 mg tablet, 100

8585W

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	109.20	37.70	Trileptal [NV]

oxcarbazepine 60 mg/mL oral liquid, 250 mL

8588B

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2	5	..	*130.15	37.70	Trileptal [NV]

oxcarbazepine 600 mg tablet, 100

8586X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	175.47	37.70	Trileptal [NV]

■ PAMIDRONATE DISODIUM

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

Symptomatic Paget disease of bone

pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial

8462J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	..	..	*84.25	37.70	Pamisol [HH]

■ 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

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.

Treatment of neutropenia should continue until recovery of the neutrophil count to at least 500 cells per cubic millimetre.

Patients who have had a previous invasive fungal infection should have secondary prophylaxis during subsequent episodes of neutropenia.

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

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.

posaconazole 100 mg tablet: modified release, 24

10460M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	..	..	877.66	37.70	Noxafil [MK]

■ PRAMIPEXOLE

Caution Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

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

Parkinson disease

pramipexole hydrochloride monohydrate 1 mg tablet, 100

9153R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	121.69	37.70	^a APO-Pramipexole [TX] ^a Pramipexole GH [GQ] ^a Simipex 1 [QA]	^a Pramipexole AN [EA] ^a Sifrol [BY] ^a Simpral [AF]

pramipexole hydrochloride monohydrate 125 microgram tablet, 30

9151P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	..	..	14.31	15.48	^a APO-Pramipexole [TX] ^a Pramipexole GH [GQ] ^a Simipex 0.125 [QA]	^a Pramipexole AN [EA] ^a Sifrol [BY] ^a Simpral [AF]

pramipexole hydrochloride monohydrate 250 microgram tablet, 100

9152Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	35.91	37.08	^a APO-Pramipexole [TX] ^a Pramipexole GH [GQ] ^a Simipex 0.25 [QA]	^a Pramipexole AN [EA] ^a Sifrol [BY] ^a Simpral [AF]

■ PRAMIPEXOLE

Caution Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.
Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

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.

Restricted benefit

Parkinson disease

pramipexole hydrochloride monohydrate 1.5 mg tablet: modified release, 30 tablets

3420B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	56.31	37.70	Sifrol ER [BY]

pramipexole hydrochloride monohydrate 2.25 mg tablet: modified release, 30 tablets

5143Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	79.27	37.70	Sifrol ER [BY]

pramipexole hydrochloride monohydrate 3 mg tablet: modified release, 30 tablets

3421C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	110.56	37.70	Sifrol ER [BY]

pramipexole hydrochloride monohydrate 3.75 mg tablet: modified release, 30 tablets

5145T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	133.51	37.70	Sifrol ER [BY]

pramipexole hydrochloride monohydrate 375 microgram tablet: modified release, 30 tablets

3418X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	22.09	23.26	Sifrol ER [BY]

pramipexole hydrochloride monohydrate 4.5 mg tablet: modified release, 30 tablets

3422D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	160.64	37.70	Sifrol ER [BY]

pramipexole hydrochloride monohydrate 750 microgram tablet: modified release, 30 tablets

3419Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	33.36	34.53	Sifrol ER [BY]

■ PRAMIPEXOLE

Caution Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.
Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Note This drug is not PBS-subsidised for Restless Legs Syndrome secondary to other causes

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

Primary severe restless legs syndrome

Clinical criteria:

Patient must manifest all 4 diagnostic criteria for Restless Legs Syndrome, **AND**

Patient must have a baseline International Restless Legs Syndrome Rating Scale (IRLSRS) score greater than or equal to 21 points prior to initiation of pramipexole.

The date and IRLSRS score must be documented in the patient's medical records at the time pramipexole treatment is initiated.

The diagnostic criteria for Restless Legs Syndrome are:

- (a) An urge to move the legs usually accompanied or caused by unpleasant sensations in the legs; and
- (b) The urge to move or unpleasant sensations begin or worsen during periods of rest or inactivity such as lying or sitting; and
- (c) The urge to move or unpleasant sensations are partially or totally relieved by movement, such as walking or stretching, at least as long as the activity continues; and
- (d) The urge to move or unpleasant sensations are worse in the evening or night than during the day or only occur during the evening or night.

pramipexole hydrochloride monohydrate 125 microgram tablet, 30

9393J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	14.31	15.48	Sifrol [BY]

pramipexole hydrochloride monohydrate 250 microgram tablet, 100

9394K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	35.91	37.08	Sifrol [BY]

■ QUINAGOLIDE**Restricted benefit**

Pathological hyperprolactinaemia

Clinical criteria:

Patient must be one in whom surgery is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

Patient must have had surgery for this condition with incomplete resolution.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

Patient must be one in whom radiotherapy is not indicated.

Restricted benefit

Pathological hyperprolactinaemia

Clinical criteria:

Patient must have had radiotherapy for this condition with incomplete resolution.

quinagolide 25 microgram tablet [3 tablets] (&) quinagolide 50 microgram tablet [3 tablets], 6

8860H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	14.81	15.98	Norprolac [FP]

quinagolide 75 microgram tablet, 30

8822H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	54.29	37.70	Norprolac [FP]

■ RASAGILINE

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

Parkinson disease

RASAGILINE Tablet 1 mg (as mesilate), 30

1952R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	115.12	37.70	Azilect [LU]

■ RILUZOLE

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

Amyotrophic lateral sclerosis
Treatment Phase: Initial treatment

Clinical criteria:

The condition must be diagnosed by a neurologist, **AND**
Patient must not have had the disease for more than 5 years, **AND**
Patient must have at least 60 percent of predicted forced vital capacity within the 2 months before commencing therapy with this drug, **AND**
Patient must be ambulatory; OR
Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, **AND**
Patient must not have undergone a tracheostomy, **AND**
Patient must not have experienced respiratory failure.
The date of diagnosis and the date and results of spirometry (in terms of percent of predicted forced vital capacity) must be supplied with the initial authority application.

Authority required

Amyotrophic lateral sclerosis
Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug, **AND**
Patient must be ambulatory; OR
Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, **AND**
Patient must not have undergone a tracheostomy, **AND**
Patient must not have experienced respiratory failure.

riluzole 50 mg tablet, 56

8664B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	361.36	37.70	^a APO-Riluzole [TX] ^a Rilutek [SW]	^a Pharmacor Riluzole [CR] ^a Riluzole Sandoz [SZ]

▪ **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.

Restricted benefit

Migraine attack

Clinical criteria:

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

rizatriptan 10 mg wafer, 2

9313E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*26.69	27.86	Maxalt [MK]

▪ **SALCATONIN**

Note The maximum quantities for salcatonin shown represent the number of individual ampoules and NOT multiples of the manufacturer's packs. The pack size for both strengths is five ampoules.

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

Symptomatic Paget disease of bone

Restricted benefit

Hypercalcaemia

Clinical criteria:

The treatment must be initiated in a hospital.

salcatonin 100 international units/mL injection, 5 x 1 mL ampoules

2997R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	3	5	..	*151.05	37.70	Miacalcin 100 [NV]

▪ **SECUKINUMAB**

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, secukinumab and ustekinumab, for adult patients with severe chronic plaque

psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
- (iii) patients who wish to recommence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab, etanercept and secukinumab, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

Grandfather patients (secukinumab only).

Applications for patients who commenced treatment with secukinumab for chronic plaque psoriasis prior to 1 September 2015 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

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

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

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

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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 Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 3, Whole body (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, **AND**

Patient must have been receiving treatment with this drug for this condition prior to 1 September 2015, **AND**

Patient must have had a Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing treatment with this drug, **AND**

Patient must have demonstrated a response to treatment as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with this drug (whole body), **AND**

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

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

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug) and the most recent PASI assessment; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

The most recent PASI assessment must be no more than 1 month old at the time of application.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

Note A PASI assessment of the patient's response to this initial PBS-subsidised course of therapy must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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

Complex Drugs

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, **AND**

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**

Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

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

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

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

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 3, Face, hand, foot (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**

Patient must have been receiving treatment with this drug for this condition prior to 1 September 2015, **AND**

Patient must have had disease, prior to treatment with this drug, classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores

for erythema, thickness and scaling were rated as severe or very severe; or (ii) the skin area affected was 30% or more of the face, palm of a hand or sole of a foot, **AND**

Patient must have demonstrated a response to treatment as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with this drug (face, hand, foot), **AND**

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

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

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug) and the most recent PASI assessment; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

The most recent PASI assessment must be no more than 1 month old at the time of application.

The PASI assessment must be performed on the same affected area as assessed at baseline or prior to initiation of treatment with this drug.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

Note A PASI assessment of the patient's response to this initial PBS-subsidised course of therapy must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**

Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

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

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

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

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 3, Whole body or Face, hand, foot (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) or Continuing treatment, Whole body or Face, hand, foot - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 3, Whole body (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) restriction to complete 24 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 3, Face, hand, foot (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) restriction to complete 24 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**

The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

secukinumab 150 mg/mL injection, 2 x 1 mL injection devices

10425Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1763.56	37.70	Cosentyx [NV]

■ SECUKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, secukinumab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
- (iii) patients who wish to recommence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab, etanercept and secukinumab, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

Grandfather patients (secukinumab only).

Applications for patients who commenced treatment with secukinumab for chronic plaque psoriasis prior to 1 September 2015 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

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

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

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

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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 Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**

Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

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

-
- (a) a completed authority prescription form; and
 - (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
 - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
 - (iii) the signed patient and prescriber acknowledgements.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.
In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, **AND**

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**

Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

- (ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to

respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**

Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

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

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

- (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
- (iii) the signed patient and prescriber acknowledgements.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**

Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

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

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

- Note** It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.
- Note** Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.
- 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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment) restriction to complete 16 weeks treatment; OR
Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment) restriction to complete 16 weeks treatment, **AND**
The treatment must be as systemic monotherapy (other than methotrexate), **AND**
The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a dermatologist.

- Note** Authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Written application for authority approval for sufficient therapy to complete a maximum of 16 weeks of treatment should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

secukinumab 150 mg/mL injection, 2 x 1 mL injection devices

10494H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	6	..	1763.56	37.70	Cosentyx [NV]

■ SELEGILINE

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

Late stage Parkinson disease

Clinical criteria:

The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

selegiline hydrochloride 5 mg tablet, 100

1973W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	52.46	37.70	^a Eldepryl [AS]	^a Selgene [AF]

■ SUMATRIPTAN

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 Pharmaceutical benefits that have the form sumatriptan tablet 50 mg (as succinate) and pharmaceutical benefits that have the form sumatriptan tablet (fast disintegrating) 50 mg (as succinate) are equivalent for the purposes of substitution.

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

Migraine attack

Clinical criteria:

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

SUMATRIPTAN Tablet (fast disintegrating) 50 mg (as succinate), 2

8885P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	^B 1.78	*19.13	18.52	^a Imigran FDT [AS]

SUMATRIPTAN Tablet 50 mg (as succinate), 2

8144P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*17.35	18.52	^a APO-Sumatriptan [TX] ^a Iptam [AL] ^a Sumatab [AF] ^a Sumatriptan Sandoz [SZ]	^a Chem mart Sumatriptan [CH] ^a Sumagran Aspen 50 [AS] ^a Sumatran [QA] ^a Terry White Chemists Sumatriptan [TW]
			^B 1.78	*19.13	18.52	^a Imigran [LN]	

sumatriptan 20 mg/actuation nasal spray, 2 actuations

8341B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	21.58	22.75	Imigran [AS]

sumatriptan 50 mg tablet, 4

1849H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	17.34	18.51	^a APO-Sumatriptan [TX] ^a Iptam [AL] ^a Sumatran [QA] ^a Sumatriptan-GA [GN] ^a Sumatriptan RBX [RA] ^a Terry White Chemists Sumatriptan [TW]	^a Chem mart Sumatriptan [CH] ^a Pharmacor Sumatriptan 50 [CR] ^a Sumatriptan AN [EA] ^a Sumatriptan generichealth [GQ] ^a Sumatriptan Sandoz [SZ]

▪ **SUNITINIB**

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 Special Pricing Arrangements apply.

Authority required

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Initial treatment

Clinical criteria:

Patient must be symptomatic (despite somatostatin analogues); OR

Patient must have disease progression, **AND**

The treatment must be as monotherapy.

Disease progression must be documented in the patient's medical records.

Patients who have developed progressive disease on everolimus are not eligible to receive PBS-subsidised sunitinib for this condition.

Patients who have developed intolerance to everolimus of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib.

sunitinib 37.5 mg capsule, 28

10464R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	5210.11	37.70	Sutent [PF]

▪ **SUNITINIB**

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 Special Pricing Arrangements apply.

Authority required

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug, **AND**

Patient must not have disease progression, **AND**

The treatment must be as monotherapy.

Patients who have progressive disease with this drug are no longer eligible for PBS-subsidised treatment with this drug.

sunitinib 37.5 mg capsule, 28

10473F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	5210.11	37.70	Sutent [PF]

■ SUNITINIB

Note Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.

Note Patients who have developed progressive disease on pazopanib are not eligible to receive PBS-subsidised sunitinib.

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 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 sunitinib, **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 tyrosine kinase inhibitor therapy for this condition.

sunitinib 37.5 mg capsule, 28

10459L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	5210.11	37.70	Sutent [PF]

■ SUNITINIB

Note Patients who have developed intolerance to pazopanib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib.

Note Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.

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 Special Pricing Arrangements apply.

Authority required

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

Clinical criteria:

Patient must meet the Memorial Sloan Kettering Cancer Centre (MSKCC) low to intermediate risk group criteria, **AND**

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

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

Patients who have developed progressive disease on pazopanib are not eligible to receive PBS-subsidised sunitinib.

sunitinib 37.5 mg capsule, 28

10504W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	5210.11	37.70	Sutent [PF]

■ SUNITINIB

Note Sunitinib malate is not PBS-subsidised for the treatment of patients with resectable malignant gastrointestinal stromal tumours.

Note Any queries concerning patients who are enrolled on the Sunitinib Compassionate Program 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).

Note Written applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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 Special Pricing Arrangements apply.

Authority required

Metastatic or unresectable malignant gastrointestinal stromal tumour

Treatment Phase: Initial treatment

Clinical criteria:

The treatment must be as monotherapy, **AND**

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

Patient must have previously failed or be intolerant to imatinib mesylate.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Sunitinib Malate (Sutent) PBS Authority Application for Use in the Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form; and

(3) a signed patient acknowledgement.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

Authority required

Metastatic or unresectable malignant gastrointestinal stromal tumour

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug, **AND**

The treatment must be as monotherapy, **AND**

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

Patient must not have progressive disease.

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.

Note Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS subsidised imatinib after progression on this drug

sunitinib 12.5 mg capsule, 28

9488J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1823.42	37.70	Sutent [PF]

sunitinib 25 mg capsule, 28

9489K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	3522.27	37.70	Sutent [PF]

sunitinib 37.5 mg capsule, 28

10503T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	5210.11	37.70	Sutent [PF]

sunitinib 50 mg capsule, 28

9490L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	6897.95	37.70	Sutent [PF]

▪ **TETRABENAZINE**

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)

5340

Hyperkinetic extrapyramidal disorders

tetrabenazine 25 mg tablet, 112

1330B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	355.49	37.70	iNova Pharmaceuticals (Australia) Pty Ltd [IA]

▪ **THIAMINE**

Authority required (STREAMLINED)

5139

Thiamine deficiency

Clinical criteria:

The treatment must be for prophylaxis.

Population criteria:

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

thiamine hydrochloride 100 mg tablet, 100

1070H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	2	..	13.63	14.80	Betavit [PP]

■ THYROTROPIN ALFA**Restricted benefit**

Ablation of thyroid remnant tissue

Clinical criteria:Patient must have undergone a thyroidectomy, **AND**The treatment must be in combination with radioactive iodine, **AND**

Patient must not have a known metastatic disease.

thyrotropin alfa 900 microgram injection, 2 x 900 microgram vials

2700D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	1893.00	37.70	Thyrogen [GZ]

■ TOPIRAMATE**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)**5290**

Seizures

Clinical criteria:

Patient must have partial epileptic seizures; OR

Patient must have primary generalised tonic-clonic seizures; OR

Patient must have seizures of the Lennox-Gastaut syndrome, **AND**The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, **AND**

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

topiramate 100 mg tablet, 60

8165R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	46.33	37.70	^a APO-Topiramate [TX] ^a RBX Topiramate [RA] ^a Topamax [JC] ^a Topiramate GH [GQ]	^a Epiramax 100 [QA] ^a Tamate [AF] ^a Topiramate AN [EA] ^a Topiramate Sandoz [SZ]

topiramate 200 mg tablet, 60

8166T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	70.76	37.70	^a APO-Topiramate [TX] ^a RBX Topiramate [RA] ^a Topamax [JC] ^a Topiramate GH [GQ]	^a Epiramax 200 [QA] ^a Tamate [AF] ^a Topiramate AN [EA] ^a Topiramate Sandoz [SZ]

■ TOPIRAMATE**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)**5173**

Seizures

Clinical criteria:

Patient must have partial epileptic seizures; OR

Patient must have primary generalised tonic-clonic seizures; OR

Patient must have seizures of the Lennox-Gastaut syndrome, **AND**The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, **AND**

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

topiramate 15 mg capsule, 60

8371N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	20.54	21.71	Topamax Sprinkle [JC]

topiramate 25 mg capsule, 60

8372P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	24.10	25.27	Topamax Sprinkle [JC]

topiramate 50 mg capsule, 60

8520K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	33.22	34.39	Topamax Sprinkle [JC]

■ TOPIRAMATE

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)

5290

Seizures

Clinical criteria:

Patient must have partial epileptic seizures; OR

Patient must have primary generalised tonic-clonic seizures; OR

Patient must have seizures of the Lennox-Gastaut syndrome, **AND**

The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs, **AND**

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

Authority required (STREAMLINED)

5325

Migraine

Clinical criteria:

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

Patient must have experienced an average of 3 or more migraines per month over a period of at least 6 months, **AND**

Patient must have a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; OR

Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker, **AND**

Patient must have a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk; OR

Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with pizotifen.

Details of the contraindication and/or intolerance(s) must be documented in the patient's medical records when treatment is initiated.

topiramate 25 mg tablet, 60

8163P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	24.32	25.49	^a APO-Topiramate [TX] ^a RBX Topiramate [RA] ^a Topamax [JC] ^a Topiramate GH [GQ]	^a Epiramax 25 [QA] ^a Tamate [AF] ^a Topiramate AN [EA] ^a Topiramate Sandoz [SZ]

topiramate 50 mg tablet, 60

8164Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	5	..	33.26	34.43	^a APO-Topiramate [TX] ^a RBX Topiramate [RA] ^a Topamax [JC] ^a Topiramate GH [GQ]	^a Epiramax 50 [QA] ^a Tamate [AF] ^a Topiramate AN [EA] ^a Topiramate Sandoz [SZ]

■ USTEKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, secukinumab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from

this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iii) patients who wish to recommence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab, etanercept and secukinumab, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

Grandfather patients (secukinumab only).

Applications for patients who commenced treatment with secukinumab for chronic plaque psoriasis prior to 1 September 2015 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response.

For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course.

Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

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

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

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

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, **AND**

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**

Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

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

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

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

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**

Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

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

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

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**

The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

ustekinumab 45 mg/0.5 mL injection, 1 x 0.5 mL vial

9305R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	4601.93	37.70	Stelara [JC]

■ USTEKINUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, secukinumab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or
- (iii) patients who wish to recommence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab, etanercept and secukinumab, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

Grandfather patients (secukinumab only).

Applications for patients who commenced treatment with secukinumab for chronic plaque psoriasis prior to 1 September 2015 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

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

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

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

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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

Note Special Pricing Arrangements apply.

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**

Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
 - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
 - (iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, **AND**

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**

Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**

Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

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

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**

Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

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

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 28 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment) restriction to complete 28 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 28 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment) restriction to complete 28 weeks treatment, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 28 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

ustekinumab 45 mg/0.5 mL injection, 1 x 0.5 mL vial

9304Q

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	2	..	4601.93	37.70	Stelara [JC]

■ ZONISAMIDE

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)

4928

Partial epileptic seizures

Clinical criteria:

The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

zonisamide 100 mg capsule, 56

9390F

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
2	5	..	*89.55	37.70	Zonegran [SA]

zonisamide 25 mg capsule, 56

9388D

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	24.66	25.83	Zonegran [SA]

zonisamide 50 mg capsule, 56

9389E

NP

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	5	..	34.16	35.33	Zonegran [SA]

Highly Specialised Drugs Program (Private Hospital)

■ IBANDRONIC ACID

Authority required

Bone metastases

Clinical criteria:

The condition must be due to breast cancer.

ibandronic acid 6 mg/6 mL injection, 1 x 6 mL vial

9619G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	361.94	Bondronat [RO]

■ INFLIXIMAB

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe active psoriatic arthritis, **AND**

Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**

Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**

Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR

Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

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

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

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

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

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

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

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

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

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis, **AND**

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**

Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, **AND**

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

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

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

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

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
 - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
 - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

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

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

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

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

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 22 weeks treatment, **AND**

The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

Note Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis, **AND**

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**

Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**

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

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

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

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

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

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

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

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

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

(1) a completed authority prescription form; and

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

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

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- (ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
- (iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

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

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

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

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

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

infliximab 100 mg injection, 1 x 100 mg vial

6496X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	788.70	Remicade [JC]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, secukinumab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iii) patients who wish to recommence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab, etanercept and secukinumab, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

Grandfather patients (secukinumab only).

Applications for patients who commenced treatment with secukinumab for chronic plaque psoriasis prior to 1 September 2015 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

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

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

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

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**

Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; **OR**

Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
 - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
 - (iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, **AND**

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**

Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
 - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**

Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

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

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**

Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

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

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

-
- (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
- (ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment) restriction to complete 22 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment) restriction to complete 22 weeks treatment, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, **AND**

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**

Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

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

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

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

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**

Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

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

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

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**

The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs

infliximab 100 mg injection, 1 x 100 mg vial

9617E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	788.70	Remicade [JC]

▪ PAMIDRONATE DISODIUM**Authority required**

Hypercalcaemia of malignancy

Clinical criteria:

Patient must have a malignancy refractory to anti-neoplastic therapy.

pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial

6287X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	2	..	*79.59	Pamisol [HH]

▪ PAMIDRONATE DISODIUM**Authority required**

Hypercalcaemia of malignancy

Clinical criteria:

Patient must have a malignancy refractory to anti-neoplastic therapy.

Authority required

Multiple myeloma

Authority required

Bone metastases

Clinical criteria:

The condition must be due to breast cancer.

pamidronate disodium 90 mg/10 mL injection, 1 x 10 mL vial

6289B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	114.03	Pamisol [HH]

▪ ZOLEDRONIC ACID

Note Special Pricing Arrangements apply.

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/5 mL injection, 1 x 5 mL vial

6371H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	474.93	Zometa [NV]

Highly Specialised Drugs Program (Public Hospital)

■ IBANDRONIC ACID

Authority required (STREAMLINED)

5291

Bone metastases

Clinical criteria:

The condition must be due to breast cancer.

ibandronic acid 6 mg/6 mL injection, 1 x 6 mL vial

5750P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	341.36	Bondronat [RO]

■ INFLIXIMAB

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe active psoriatic arthritis, **AND**

Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition, **AND**

Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**

Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR

Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

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

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

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

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

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

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

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

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

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment – Initial 2 (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis, **AND**

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle, **AND**

Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle, **AND**

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

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

- (1) a completed authority prescription form; and
- (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug.

Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased.

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

Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

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

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

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

Note The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted to the Department of Human Services no later than 4 weeks from the cessation of the treatment

course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle. There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and

(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and

(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response

assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
(ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

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

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

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

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

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 22 weeks treatment, **AND**

The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

Note Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have a documented history of severe active psoriatic arthritis, **AND**

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**

Patient must demonstrate, at the time of application, an adequate response to treatment with this drug, **AND**

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

Population criteria:

Patient must be an adult.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

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

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

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

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

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

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

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

(1) a completed authority prescription form; and

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

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Note Patients who fail to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this Treatment Cycle. Patients may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE PSORIATIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, certolizumab pegol, etanercept, golimumab and infliximab for adult patients with severe active psoriatic arthritis.

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological agents at any 1 time.

Where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, certolizumab pegol, etanercept, golimumab and infliximab only.

Patients receiving PBS-subsidised treatment for psoriatic arthritis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Following demonstration of response to initial treatment, these biological agents are available under the PBS for continuing treatment as set out in the continuing treatment restriction for each agent.

Once patients have either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological therapy before they are eligible to commence another Cycle [further details are under '(5) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' below].

The duration of the break in therapy will be measured from the date the last approval for PBS-subsidised treatment was granted in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Cycle.

Within the same Cycle, patients are not allowed to fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for any biological agent, they must change to an alternate agent which they have not previously failed, if they wish to continue PBS-subsidised biological treatment.

Patients for whom a break in PBS-subsidised therapy of less than 5 years has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular treatment Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe active psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

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- (i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); and
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; and
(iii) patients wish to re-commence treatment with a specific biological agent following a break in PBS-subsidised therapy with that specific agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept and golimumab, 18 to 20 weeks of therapy for certolizumab pegol (depending upon the dosing regimen), and 22 weeks of therapy for infliximab. It is recommended that patients be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological agent supply.

Patients must be assessed for response to any course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

Grandfather patients - certolizumab pegol only.

For patients who commenced treatment with certolizumab pegol for psoriatic arthritis prior to 1 April 2015, applications for initial PBS-subsidised treatment as continuing therapy may be made under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with any biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment for all agents. Approval will be based on the criteria included in the relevant restriction.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological agent, patients may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

Patients are eligible to receive continuing biological treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

Patients must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased. Where a response assessment is not submitted within these timeframes, patients will be deemed to have failed to respond to treatment with that biological agent.

(3) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate biological agent without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements.

Patients may swap to an alternate biological agent at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological agent at the time of the application or not.

Within a Treatment Cycle patients may alternate between therapy with any biological agent of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological agent previously; or
- (ii) they have demonstrated an adequate response to that particular biological agent if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment 3 times in this Treatment Cycle.

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

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the biological agent the patient is ceasing.

(4) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated based on the baseline measurements of the indices of disease severity submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment application is submitted within a treatment Cycle and these revised baseline measurements will be used to assess response.

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

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

Patients who wish to trial a second or subsequent treatment Cycle following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment with respect to both the indices of disease severity. Patients must have received treatment with methotrexate and sulfasalazine or leflunomide, at an adequate dose, for a minimum of 3 months at the time the ESR or CRP levels and the active joint counts are measured.

Authority required

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Treatment criteria:

Must be treated by a rheumatologist; OR

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

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

infliximab 100 mg injection, 1 x 100 mg vial

5756Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	751.70	Remicade [JC]

■ INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological agents adalimumab, etanercept, infliximab, secukinumab and ustekinumab, for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological agents' appears in notes and restrictions, it refers to adalimumab, etanercept, infliximab, secukinumab and ustekinumab only.

Patients receiving PBS-subsidised treatment for chronic plaque psoriasis are able to commence a 'Biological Treatment Cycle' (Cycle), where they may trial biological agents without having to meet the initial treatment criteria, that is they will not need to experience a disease flare, when swapping to an alternate agent. Under these interchangeability arrangements, within a single Cycle, patients may receive long-term treatment with a biological agent as long as they sustain a response to therapy.

Patients are eligible for PBS-subsidised treatment with only 1 biological agent at any 1 time.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological agent more than once. Therefore once a patient fails to meet the response criteria for a PBS-subsidised biological agent, they must change to an alternate agent if they wish to continue PBS-subsidised biological treatment. A patient still in their first Treatment Cycle who, prior to 1 December 2007, under the interchangeability arrangements in effect at the time, was authorised to receive PBS-subsidised initial treatment for chronic plaque psoriasis with the same agent twice is exempt from this condition in respect of applications approved prior to 1 December 2007.

Patients must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a Treatment Cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological agent therapy before they are eligible to commence the next Cycle. The duration of the break in therapy is measured from the date of the last approval for PBS-subsidised biological agent treatment in the most recent Cycle to the date of the first application for initial treatment with a biological agent under the new Treatment Cycle.

Patients for whom a break in PBS-subsidised therapy of less than 5 years duration has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, may commence a further course of treatment within that Cycle.

Patients for whom a break in PBS-subsidised therapy of 5 years or more has occurred, and, who have failed therapy fewer than 3 times within a particular Cycle, as defined in the relevant restriction, are eligible to commence a new Cycle.

There is no limit to the number of Biological Treatment Cycles a patient may undertake in their lifetime.

How to prescribe biological agents for the treatment of severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Application for approval for initial treatment.

Applications for a course of initial treatment should be made in the following situations:

(i) patients have received no prior PBS-subsidised biological treatment and wish to commence such therapy (Initial 1); or
(ii) patients have received prior PBS-subsidised biological therapy and wish to trial an alternate agent (Initial 2) [further details are under '(4) Swapping therapy' below]; or

(iii) patients who wish to recommence treatment following a break in PBS-subsidised therapy with that agent (Initial 2).

All applications for initial treatment for non-grandfather patients will be limited to provide for a maximum of 16 weeks of treatment in the case of adalimumab, etanercept and secukinumab, 22 weeks of treatment in the case of infliximab and 28 weeks of treatment in the case of ustekinumab.

Grandfather patients (secukinumab only).

Applications for patients who commenced treatment with secukinumab for chronic plaque psoriasis prior to 1 September 2015 may be made for initial PBS-subsidised treatment as continuing therapy under the relevant initial treatment restriction (Initial 3). These patients access the PBS interchangeability arrangements in the same way as new patients who have not been treated with a biological agent prior to PBS listing of that agent.

Applications for initial PBS-subsidised treatment for grandfather patients will provide for a maximum of 24 weeks of treatment. Approval will be based on the criteria included in the relevant restriction.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological agent, a PASI assessment must be conducted after at least 12 weeks of treatment. This assessment must be submitted to the Department of Human Services within 1 month of the completion of this initial treatment course. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Application for continuing treatment.

Following the completion of an initial treatment course with a biological agent to which an adequate response has been demonstrated, patients may qualify to receive up to 24 weeks of continuing treatment with that biological agent. Patients are eligible to continue to receive continuous treatment with 24 week courses providing they continue to sustain a response. For second and subsequent courses of PBS-subsidised treatment with a specific biological agent it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course. Where a response assessment is not submitted to the Department of Human Services within these timeframes, patients will be deemed to have failed to sustain a response to treatment with that biological agent. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

(4) Swapping therapy.

Once an authority for initial treatment with the first PBS-subsidised biological agent is approved, patients may swap to an alternate agent within the same Treatment Cycle without having to requalify with respect to disease severity (i.e. a PASI score of greater than 15), or prior treatment requirements.

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

Patients may trial an alternate biological agent at any time, regardless of whether they are receiving therapy with a biological agent at the time of the application or not. However, they cannot swap to a particular agent if they have failed to respond to treatment with that particular agent within the same Cycle.

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

To avoid confusion, applications for patients who wish to swap to an alternate biological agent should be accompanied by the approved authority prescription or remaining repeats for the agent being ceased.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been demonstrated, based on the baseline PASI assessment submitted with the first authority application for a biological agent. However, prescribers may provide new baseline measurements any time that an initial treatment authority is submitted within a Treatment Cycle and subsequent response will be assessed according to this revised PASI score.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatment applications.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Patients who wish to trial a second or subsequent Biological Treatment Cycle, following a break in PBS-subsidised biological therapy of at least 5 years, must requalify for initial treatment according to the criteria of the relevant restriction and index of disease severity. Patients must have had at least 1 prior treatment, as listed in the criteria, for a minimum of 6 weeks, and must have a PASI assessment conducted preferably whilst still on treatment, but no later than 1 month following cessation of treatment. The PASI assessment must be no older than 1 month at the time of application.

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

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Whole body (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**

Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; **OR**

Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (whole body), **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 1 month old at the time of application.

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
 - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and
 - (iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, **AND**

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**

Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
 - (ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient (no prior biological agent) or patient recommencing treatment after a break of 5 years or more)

Clinical criteria:

Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**

Patient must not have received any prior PBS-subsidised treatment with a biological agent for this condition; OR

Patient must not have received PBS-subsidised treatment with a biological agent for at least 5 years, if they have previously received PBS-subsidised treatment with a biological agent for this condition and wish to commence a new Treatment Cycle, **AND**

Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 3 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, **AND**

Patient must have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment (face, hand, foot), **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 1 month old at the time of application.

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

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]; and

(iii) the signed patient and prescriber acknowledgements.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (www.humanservices.gov.au)

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment)

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**

Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, **AND**

Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, **AND**

Patient must not have failed, or ceased to respond to, PBS-subsidised therapy with this drug for the treatment of this condition in the current Treatment Cycle, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

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

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

-
- (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
- (ii) details of prior biological treatment, including dosage, date and duration of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 3 repeats may be authorised.

Applications for patients who have demonstrated a response to PBS-subsidised treatment with this drug within this Treatment Cycle and who wish to recommence treatment with this drug within the same Cycle following a break in therapy, will only be approved where evidence of the patient's response to their most recent course of PBS-subsidised treatment with this drug has been submitted within 1 month of cessation of treatment.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

Note A PASI assessment of the patient's response to this initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment) - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Initial 1, Whole body (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2, Whole body (change or recommencement of treatment) restriction to complete 22 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 1, Face, hand, foot (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 22 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Initial 2, Face, hand, foot (change or recommencement of treatment) restriction to complete 22 weeks treatment, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Treatment criteria:

Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 22 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis, **AND**

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**

Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the prebiological treatment baseline value for this Treatment Cycle.

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

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

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

(a) a completed authority prescription form; and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

Patient must have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, **AND**

Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle, **AND**

Patient must have demonstrated an adequate response to their most recent course of treatment with this drug, **AND**

The treatment must be as systemic monotherapy (other than methotrexate), **AND**

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

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a dermatologist.

For the purposes of this restriction 'biological agent' means adalimumab, etanercept, infliximab, secukinumab or ustekinumab.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.

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

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

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
 - (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats may be authorised.

Note A PASI assessment of the patient's response must be conducted within 4 weeks prior to completion of this course of treatment. This assessment, which will be used to determine eligibility for further continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this course of treatment. Where a response assessment is not undertaken and submitted to the Department of Human Services within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. In circumstances where it is not possible to submit a response assessment within these timeframes, please call the Department of Human Services on 1800 700 270 to discuss.

Note It is recommended that an application is posted to the Department of Human Services no later than 2 weeks prior to the patient completing their current treatment course to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug.

Note Patients who fail to demonstrate a response to treatment with 3 biological agents are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may recommence a new Biological Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised biological agent was approved in this Cycle and the date of the first application under the new Cycle.

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
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR

Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**

The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**

The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

Must be treated by a dermatologist.

Note Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written application for authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment should be forwarded to:

Department of Human Services
Complex Drugs

infliximab 100 mg injection, 1 x 100 mg vial

5758C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	751.70	Remicade [JC]

▪ **PAMIDRONATE DISODIUM**

Authority required (STREAMLINED)

4433

Hypercalcaemia of malignancy

Clinical criteria:

Patient must have a malignancy refractory to anti-neoplastic therapy.

pamidronate disodium 30 mg/10 mL injection, 1 x 10 mL vial

5668H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	2	..	*68.66	Pamisol [HH]

▪ **PAMIDRONATE DISODIUM**

Authority required (STREAMLINED)

4433

Hypercalcaemia of malignancy

Clinical criteria:

Patient must have a malignancy refractory to anti-neoplastic therapy.

Authority required (STREAMLINED)

5218

Multiple myeloma

Authority required (STREAMLINED)

5291

Bone metastases

Clinical criteria:

The condition must be due to breast cancer.

pamidronate disodium 90 mg/10 mL injection, 1 x 10 mL vial

5670K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	102.98	Pamisol [HH]

▪ **ZOLEDRONIC ACID**

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

5330

Multiple myeloma

Authority required (STREAMLINED)

5403

Bone metastases

Clinical criteria:

The condition must be due to breast cancer.

Authority required (STREAMLINED)

5404

Bone metastases

Clinical criteria:

The condition must be due to castration-resistant prostate cancer.

Authority required (STREAMLINED)

5176

Hypercalcaemia of malignancy

Clinical criteria:

Patient must have a malignancy refractory to anti-neoplastic therapy.

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
	1	11	..	450.00	Zometa [NV]

Botulinum Toxin Program

▪ BOTULINUM TOXIN TYPE A

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)

5221

Blepharospasm or hemifacial spasm

Clinical criteria:

Patient must have blepharospasm; OR

Patient must have hemifacial spasm.

Population criteria:

Patient must be aged 12 years or older.

Treatment criteria:

Must be treated by a neurologist; OR

Must be treated by an ophthalmologist; OR

Must be treated by an otolaryngology head and neck surgeon; OR

Must be treated by a plastic surgeon.

Authority required (STREAMLINED)

5359

Dynamic equinus foot deformity

Clinical criteria:

The condition must be due to spasticity, **AND**

Patient must have cerebral palsy, **AND**

Patient must be ambulant.

Population criteria:

Patient must be aged from 2 to 17 years inclusive.

Treatment criteria:

Must be treated by a neurologist; OR

Must be treated by an orthopaedic surgeon; OR

Must be treated by a paediatrician; OR

Must be treated by a rehabilitation specialist.

Authority required (STREAMLINED)

5407

Dynamic equinus foot deformity

Clinical criteria:

The condition must be due to spasticity, **AND**

Patient must have cerebral palsy, **AND**

Patient must be ambulant, **AND**

Patient must have commenced PBS-subsidised treatment with Botulinum Toxin Type A Purified Neurotoxin Complex as a paediatric patient.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a neurologist; OR

Must be treated by an orthopaedic surgeon; OR

Must be treated by a paediatrician; OR

Must be treated by a rehabilitation specialist.

Authority required (STREAMLINED)

5406

Spasmodic torticollis

Clinical criteria:

Patient must have spasmodic torticollis, **AND**
The treatment must be as monotherapy; OR
The treatment must be as adjunctive therapy to current standard care.

Treatment criteria:

Must be treated by a neurologist; OR
Must be treated by a plastic surgeon; OR
Must be treated by a rehabilitation specialist.

Authority required (STREAMLINED)

5178

Moderate to severe spasticity of the upper limb

Clinical criteria:

Patient must have cerebral palsy.

Population criteria:

Patient must be aged from 2 to 17 years inclusive.

Treatment criteria:

Must be treated by a neurologist; OR
Must be treated by an orthopaedic surgeon; OR
Must be treated by a paediatrician; OR
Must be treated by a rehabilitation specialist; OR
Must be treated by a plastic surgeon.

Authority required (STREAMLINED)

5261

Moderate to severe spasticity of the upper limb

Clinical criteria:

Patient must have cerebral palsy, **AND**

Patient must have commenced PBS-subsidised treatment with Botulinum Type A Neurotoxin Complex as a paediatric patient.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a neurologist; OR
Must be treated by an orthopaedic surgeon; OR
Must be treated by a paediatrician; OR
Must be treated by a rehabilitation specialist; OR
Must be treated by a plastic surgeon.

Note Contact the Department of Human Services before commencing PBS-subsidised treatment in cerebral palsy patients who have been treated for moderate to severe spasticity of the upper limb with non-PBS-subsidised botulinum toxin prior to the age of 18.

Authority required (STREAMLINED)

5220

Moderate to severe spasticity of the upper limb following a stroke

Clinical criteria:

The condition must be moderate to severe spasticity of the upper limb/s following stroke, defined as a Modified Ashworth Scale rating of 3 or more, **AND**

The treatment must not be initiated until three months post-stroke, **AND**

The treatment must only be used as second line therapy when standard management has failed; OR

The treatment must only be used as an adjunct to physical therapy, **AND**

The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (total Botox, Dysport, and Xeomin), **AND**

The treatment must not exceed 4 treatment periods (total Botox, Dysport, and Xeomin) per upper limb per lifetime, **AND**

Patient must not have established severe contracture in the limb to be treated.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a neurologist; OR
Must be treated by an orthopaedic surgeon; OR
Must be treated by a rehabilitation specialist; OR
Must be treated by a plastic surgeon; OR
Must be treated by a geriatrician.

The date of the stroke must be documented in the patient's medical records when treatment is initiated.

Standard management includes physiotherapy and/or oral spasticity agents.

Authority required (STREAMLINED)

5408

Severe primary axillary hyperhidrosis

Clinical criteria:

Patient must have previously failed topical aluminium chloride hexahydrate after one to two months of treatment; OR
Patient must be intolerant to topical aluminium chloride hexahydrate treatment.

Population criteria:

Patient must be aged 12 years or older.

Treatment criteria:

Must be treated by a dermatologist; OR

Must be treated by a neurologist; OR

Must be treated by a paediatrician.

Maximum number of treatments per year is 3, with no less than 4 months to elapse between treatments.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

5409

Urinary incontinence

Clinical criteria:

The condition must be due to neurogenic detrusor overactivity, as demonstrated by urodynamic study, **AND**

The condition must be inadequately controlled by anti-cholinergic therapy, **AND**

Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with Botulinum Toxin Type A Neurotoxin Complex, **AND**

Patient must be willing and able to self-catheterise, **AND**

The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment, **AND**

Patient must have multiple sclerosis; OR

Patient must have a spinal cord injury; OR

Patient must be aged 18 years or older and have spina bifida.

Treatment criteria:

Must be treated by a urologist; OR

Must be treated by a urogynaecologist.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

5333

Urinary incontinence

Clinical criteria:

The condition must be due to idiopathic overactive bladder, **AND**

The condition must have been inadequately controlled by therapy involving at least two alternative anti-cholinergic agents, **AND**

Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with botulinum toxin type A neurotoxin complex, **AND**

Patient must be willing and able to self-catheterise, **AND**

The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a urologist; OR

Must be treated by a urogynaecologist.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

5262

Chronic migraine

Clinical criteria:

Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with botulinum toxin type A neurotoxin, **AND**

Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with botulinum toxin type A neurotoxin, **AND**

Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of headache days per month after two treatment cycles (each of 12 weeks duration) in order to be eligible for continuing PBS-subsidised treatment, **AND**

Patient must be appropriately managed by his or her practitioner for medication overuse headache, prior to initiation of treatment with botulinum toxin.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a neurologist.

Prophylactic migraine medications are propranolol, amitriptylin, methsergide, pizotifen, cyproheptadine or topiramate.

Note Special Pricing Arrangements apply.

botulinum toxin type A 100 units injection, 1 x 100 units vial

6103F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1708.93	37.70	Botox [AG]

■ CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)**5405**

Blepharospasm or hemifacial spasm

Clinical criteria:

Patient must have blepharospasm; OR

Patient must have hemifacial spasm.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a neurologist; OR

Must be treated by an ophthalmologist; OR

Must be treated by an otolaryngology head and neck surgeon; OR

Must be treated by a plastic surgeon.

Authority required (STREAMLINED)**5359**

Dynamic equinus foot deformity

Clinical criteria:

The condition must be due to spasticity, **AND**

Patient must have cerebral palsy, **AND**

Patient must be ambulant.

Population criteria:

Patient must be aged from 2 to 17 years inclusive.

Treatment criteria:

Must be treated by a neurologist; OR

Must be treated by an orthopaedic surgeon; OR

Must be treated by a paediatrician; OR

Must be treated by a rehabilitation specialist.

Authority required (STREAMLINED)**5332**

Dynamic equinus foot deformity

Clinical criteria:

The condition must be due to spasticity, **AND**

Patient must be an ambulant cerebral palsy patient, **AND**

Patient must have commenced on PBS-subsidised treatment with clostridium botulinum type A toxin-haemagglutinin complex as a paediatric patient.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a neurologist; OR

Must be treated by an orthopaedic surgeon; OR

Must be treated by a paediatrician; OR

Must be treated by a rehabilitation specialist.

Authority required (STREAMLINED)**5220**

Moderate to severe spasticity of the upper limb following a stroke

Clinical criteria:

The condition must be moderate to severe spasticity of the upper limb/s following stroke, defined as a Modified Ashworth Scale rating of 3 or more, **AND**

The treatment must not be initiated until three months post-stroke, **AND**

The treatment must only be used as second line therapy when standard management has failed; OR

The treatment must only be used as an adjunct to physical therapy, **AND**

The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (total Botox, Dysport, and Xeomin), **AND**

The treatment must not exceed 4 treatment periods (total Botox, Dysport, and Xeomin) per upper limb per lifetime, **AND**

Patient must not have established severe contracture in the limb to be treated.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a neurologist; OR
 Must be treated by an orthopaedic surgeon; OR
 Must be treated by a rehabilitation specialist; OR
 Must be treated by a plastic surgeon; OR
 Must be treated by a geriatrician.

The date of the stroke must be documented in the patient's medical records when treatment is initiated.

Standard management includes physiotherapy and/or oral spasticity agents.

Authority required (STREAMLINED)**5406**

Spasmodic torticollis

Clinical criteria:

Patient must have spasmodic torticollis, **AND**
 The treatment must be as monotherapy; OR
 The treatment must be as adjunctive therapy to current standard care.

Treatment criteria:

Must be treated by a neurologist; OR
 Must be treated by a plastic surgeon; OR
 Must be treated by a rehabilitation specialist.

clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 x 300 units vial

1152P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1493.01	37.70	Dysport [IS]

clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 x 500 units vial

6293F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*1336.55	37.70	Dysport [IS]

■ INCOBOTULINUMTOXINA

Caution Contraindications to treatment include known sensitivity to botulinum toxin.

Note The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

Authority required (STREAMLINED)**5360**

Blepharospasm

Clinical criteria:

Patient must have blepharospasm.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a neurologist; OR
 Must be treated by an ophthalmologist; OR
 Must be treated by an otolaryngology head and neck surgeon; OR
 Must be treated by a plastic surgeon.

Authority required (STREAMLINED)**5222**

Spasmodic torticollis

Clinical criteria:

Patient must have spasmodic torticollis, **AND**
 The treatment must be as monotherapy; OR
 The treatment must be as adjunctive therapy to current standard care.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a neurologist; OR
 Must be treated by a plastic surgeon; OR
 Must be treated by a rehabilitation specialist.

Authority required (STREAMLINED)**5220**

Moderate to severe spasticity of the upper limb following a stroke

Clinical criteria:

The condition must be moderate to severe spasticity of the upper limb/s following stroke, defined as a Modified Ashworth Scale rating of 3 or more, **AND**

The treatment must not be initiated until three months post-stroke, **AND**
 The treatment must only be used as second line therapy when standard management has failed; OR
 The treatment must only be used as an adjunct to physical therapy, **AND**

The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (total Botox, Dysport, and Xeomin), **AND**

The treatment must not exceed 4 treatment periods (total Botox, Dysport, and Xeomin) per upper limb per lifetime, **AND** Patient must not have established severe contracture in the limb to be treated.

Population criteria:

Patient must be aged 18 years or older.

Treatment criteria:

Must be treated by a neurologist; OR

Must be treated by an orthopaedic surgeon; OR

Must be treated by a rehabilitation specialist; OR

Must be treated by a plastic surgeon; OR

Must be treated by a geriatrician.

The date of the stroke must be documented in the patient's medical records when treatment is initiated.

Standard management includes physiotherapy and/or oral spasticity agents.

incobotulinumtoxinA 100 mouse LD50 units injection, 1 x 100 mouse LD50 units vial

10253P

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
3	..	..	*1171.92	37.70	Xeomin [EZ]

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

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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 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 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 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

6476W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	264.33	37.70	Omnitrope [SZ]

somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

6311E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	521.73	37.70	Omnitrope [SZ]

somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

10446T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	779.13	37.70	Omnitrope Surepal 15 [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: 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.

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.

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.

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

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a chronological age of less than 2 years, **AND**

Patient must have a documented clinical risk of hypoglycaemia, **AND**

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **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.

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. Recent growth data (height and weight, not older than three months); AND
4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; 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

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 IGF-1 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.

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 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, 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.

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 155.0cm, **AND**

Patient must not have a bone age of 13.5 years or greater.

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.

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 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.

SOMATROPIN (Recombinant human growth hormone) Injection 8 mg (24 i.u.) vial with 1.37 mL diluent cartridge (with preservative) (for use with one.click auto-injector), 1

6329D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	418.77	37.70	Saizen 8 mg click.easy [SG]

somatropin 12 international units (4 mg) injection [1 x 4 mg vial] (&) inert substance diluent [1 vial], 1 pack

6266T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	212.85	37.70	Zomacton [FP]

somatropin 18 international units (6 mg/1.03 mL) injection, 1 x 1.03 mL cartridge

5822K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	315.81	37.70	Saizen [SG]

somatropin 30 international units (10 mg) injection [1 x 10 mg vial] (&) inert substance diluent [1 x 1 mL syringe], 1 pack

6310D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	521.73	37.70	Zomacton [FP]

somatropin 36 international units (12 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

5824M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	624.69	37.70	Saizen [SG]

somatropin 60 international units (20 mg/2.5 mL) injection, 1 x 2.5 mL cartridge

3388H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1036.53	37.70	Saizen [SG]

■ **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.

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.

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 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.

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 IGF-1 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.

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

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a chronological age of less than 2 years, **AND**

Patient must have a documented clinical risk of hypoglycaemia, **AND**

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **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.

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. Recent growth data (height and weight, not older than three months); AND
4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; 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

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.

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.

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 155.0cm, **AND**

Patient must not have a bone age of 13.5 years or greater.

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.

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 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 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 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 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 prepubertal.

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 18 international units (6 mg) injection [1 x 6 mg cartridge] (&) inert substance diluent [1 x 3.15 mL syringe], 1 pack

6169Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	315.81	37.70	Humatrope [LY]

somatropin 36 international units (12 mg) injection [1 x 12 mg cartridge] (&) inert substance diluent [1 x 3.15 mL syringe], 1 pack

6170R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	624.69	37.70	Humatrope [LY]

somatropin 72 international units (24 mg) injection [1 x 24 mg cartridge] (&) inert substance diluent [1 x 3.15 mL syringe], 1 pack

6345Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1234.93	37.70	Humatrope [LY]

▪ **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.

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.

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 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.

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.

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. 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

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a chronological age of less than 2 years, **AND**

Patient must have a documented clinical risk of hypoglycaemia, **AND**

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **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.

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. Recent growth data (height and weight, not older than three months); AND
4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; 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

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.

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 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, 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.

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 155.0cm, **AND**

Patient must not have a bone age of 13.5 years or greater.

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.

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 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 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 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 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 167.7cm; 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.

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

6295H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	264.33	37.70	Norditropin SimpleXx [NO]

somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

6296J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	521.73	37.70	Norditropin SimpleXx [NO]

somatropin 30 international units (10 mg/2 mL) injection, 1 x 2 mL cartridge

9604L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	521.73	37.70	NutropinAq [IS]

somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

6297K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	779.13	37.70	Norditropin SimpleXx [NO]

■ 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

Note Special Pricing Arrangements apply.

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.

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.

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.

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

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a chronological age of less than 2 years, **AND**

Patient must have a documented clinical risk of hypoglycaemia, **AND**

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **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.

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. Recent growth data (height and weight, not older than three months); AND
4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; 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

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.

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 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, 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.

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 155.0cm, AND

Patient must not have a bone age of 13.5 years or greater.

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.

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 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 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 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 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 167.7cm; 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.

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

5818F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	335.05	37.70	Norditropin FlexPro [NO]

somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

5819G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	663.17	37.70	Norditropin FlexPro [NO]

somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

5820H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	991.29	37.70	Norditropin FlexPro [NO]

▪ **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.

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 IGF-1 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.

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 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.

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.

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

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a chronological age of less than 2 years, **AND**

Patient must have a documented clinical risk of hypoglycaemia, **AND**

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **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.

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. Recent growth data (height and weight, not older than three months); AND
4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; 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

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.

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 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, 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.

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 155.0cm, **AND**

Patient must not have a bone age of 13.5 years or greater.

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.

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 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 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 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 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 167.7cm; 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.

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.

Authority required

Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); OR

Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist, **AND**

Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with no sleep disorders identified; OR

Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified which are not of sufficient severity to require treatment; OR

Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified for which the patient is currently receiving ameliorative treatment, **AND**

Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height, **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 chronological age of 18 years or greater.

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 minimum of 6 months of recent growth data (height, weight and waist circumference). The most recent data must not be older than three months; AND
4. The date that skeletal maturity was achieved (if applicable); AND
5. (a) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome; OR
 (b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist
6. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months and any sleep disorders identified via polysomnography that required treatment have been addressed; 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 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 (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1

9586M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	624.69	37.70	Genotropin GoQuick [PF]

SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1

9585L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	264.33	37.70	Genotropin GoQuick [PF]

somatropin 1.8 international units (600 microgram) injection [7 x 600 microgram syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

9628R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	223.15	37.70	Genotropin MiniQuick [PF]

somatropin 2.4 international units (800 microgram) injection [7 x 800 microgram syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

6313G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	295.22	37.70	Genotropin MiniQuick [PF]

somatropin 3 international units (1 mg) injection [7 x 1 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

6314H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	367.29	37.70	Genotropin MiniQuick [PF]

somatropin 3.6 international units (1.2 mg) injection [7 x 1.2 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

6315J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	439.36	37.70	Genotropin MiniQuick [PF]

somatropin 36 international units (12 mg) injection [1 x 12 mg cartridge] (&) inert substance diluent [1 x 1 mL cartridge], 1 pack

6312F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	624.69	37.70	Genotropin [PF]

somatropin 4.2 international units (1.4 mg) injection [7 x 1.4 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

6316K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	511.43	37.70	Genotropin MiniQuick [PF]

somatropin 4.8 international units (1.6 mg) injection [7 x 1.6 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

6317L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	583.51	37.70	Genotropin MiniQuick [PF]

somatropin 5.4 international units (1.8 mg) injection [7 x 1.8 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

6318M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	655.58	37.70	Genotropin MiniQuick [PF]

somatropin 6 international units (2 mg) injection [7 x 2 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

6319N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	727.65	37.70	Genotropin MiniQuick [PF]

■ 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.

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.

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 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.

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 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 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); 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 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 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); 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 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, **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.

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.

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.

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

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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.

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 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 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 (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.

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 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), 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 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, **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 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

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), 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 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, **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.

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**

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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), 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 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, **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 IGF-1 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.

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 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

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

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 risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **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), 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 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 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 a chronological age of less than 2 years, **AND**

Patient must have a documented clinical risk of hypoglycaemia, **AND**

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **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.

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 a documented clinical risk of hypoglycaemia; **AND**
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; **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. 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 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 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 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 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 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 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 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 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.

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), 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 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 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 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.

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 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 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, **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.

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
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), 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 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, **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.

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.

SOMATROPIN (Recombinant human growth hormone) Injection 8 mg (24 i.u.) vial with 1.37 mL diluent cartridge (with preservative) (for use with one.click auto-injector), 1

10433D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	418.77	37.70	Saizen 8 mg click.easy [SG]

somatropin 12 international units (4 mg) injection [1 x 4 mg vial] (&) inert substance diluent [1 vial], 1 pack

10452D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	212.85	37.70	Zomacton [FP]

somatropin 18 international units (6 mg/1.03 mL) injection, 1 x 1.03 mL cartridge

10462P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	315.81	37.70	Saizen [SG]

somatropin 30 international units (10 mg) injection [1 x 10 mg vial] (&) inert substance diluent [1 x 1 mL syringe], 1 pack

10440L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	521.73	37.70	Zomacton [FP]

somatropin 36 international units (12 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

10483R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	624.69	37.70	Saizen [SG]

somatropin 60 international units (20 mg/2.5 mL) injection, 1 x 2.5 mL cartridge

10497L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1036.53	37.70	Saizen [SG]

■ **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), 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 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, **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.

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), 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 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, **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.

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), 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 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, **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.

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), 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 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, **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.

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), 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 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, **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.

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

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), 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 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, **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.

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), 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 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, **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.

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), 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 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, **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.

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 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), 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 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, **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.

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), 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 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, **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 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.

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), 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 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, **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.

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 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

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

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 risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **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), 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 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, **AND**

Patient must have a chronological age of less than 2 years, **AND**

Patient must have a documented clinical risk of hypoglycaemia, **AND**

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **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.

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 a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; 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

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), 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 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, **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.

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), 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 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, **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 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 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.

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), 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 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, **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.

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), 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 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, **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.

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.

SOMATROPIN (Recombinant human growth hormone) Injection 8 mg (24 i.u.) vial with 1.37 mL diluent cartridge (with preservative) (for use with one.click auto-injector), 1

10471D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	418.77	37.70	Saizen 8 mg click.easy [SG]

somatropin 12 international units (4 mg) injection [1 x 4 mg vial] (&) inert substance diluent [1 vial], 1 pack

10447W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	212.85	37.70	Zomacton [FP]

somatropin 18 international units (6 mg/1.03 mL) injection, 1 x 1.03 mL cartridge

10458K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	315.81	37.70	Saizen [SG]

somatropin 30 international units (10 mg) injection [1 x 10 mg vial] (&) inert substance diluent [1 x 1 mL syringe], 1 pack

10455G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	521.73	37.70	Zomacton [FP]

somatropin 36 international units (12 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

10495J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	624.69	37.70	Saizen [SG]

somatropin 60 international units (20 mg/2.5 mL) injection, 1 x 2.5 mL cartridge

10442N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1036.53	37.70	Saizen [SG]

■ 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 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 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 (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 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 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), 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 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, **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), 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 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, **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), 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 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, **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), 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 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, **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), 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 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, **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 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 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, **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

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), 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 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, **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), 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 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, **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

10427T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	264.33	37.70	Omnitrope [SZ]

somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

10441M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	521.73	37.70	Omnitrope [SZ]

somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

10490D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	779.13	37.70	Omnitrope Surepal 15 [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.

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.

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 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.

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.

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.

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.

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.

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 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 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 (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.

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 a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **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 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.

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), 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 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, **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 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

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

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- (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), 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 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, **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 IGF-1 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.

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 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 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 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 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 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 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 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.

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 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

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

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 risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **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), 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 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, **AND**

Patient must have a chronological age of less than 2 years, **AND**

Patient must have a documented clinical risk of hypoglycaemia, **AND**

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **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.

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 a documented clinical risk of hypoglycaemia; AND

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4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; 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. 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), 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 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, **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.

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), 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 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, **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 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, 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.

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 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 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, **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.

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**
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), 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 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, **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 mosaik 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.

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**

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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), 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 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, **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.

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

10469B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	264.33	37.70	Norditropin SimpleXx [NO]

somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

10439K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	521.73	37.70	Norditropin SimpleXx [NO]

somatropin 30 international units (10 mg/2 mL) injection, 1 x 2 mL cartridge

10478L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	521.73	37.70	NutropinAq [IS]

somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

10468Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	779.13	37.70	Norditropin SimpleXx [NO]

▪ **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.

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.

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 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.

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.

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.

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.

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.

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.

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 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 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 prepubertal.

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), 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 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, **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 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

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), 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 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, **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.

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 somatotropin 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), 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 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, **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.

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 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

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

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 risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **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), 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 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, **AND**

Patient must have a chronological age of less than 2 years, **AND**

Patient must have a documented clinical risk of hypoglycaemia, **AND**

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **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.

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 a documented clinical risk of hypoglycaemia; **AND**

4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; **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. 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), 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 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, **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.

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 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 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 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 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 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 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 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 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, 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.

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 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 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, **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.

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
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), 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 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, **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.

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), 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 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, **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 prepubertal.

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 18 international units (6 mg) injection [1 x 6 mg cartridge] (&) inert substance diluent [1 x 3.15 mL syringe], 1 pack

10482Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	315.81	37.70	Humatrope [LY]

somatropin 36 international units (12 mg) injection [1 x 12 mg cartridge] (&) inert substance diluent [1 x 3.15 mL syringe], 1 pack

10487Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	624.69	37.70	Humatrope [LY]

somatropin 72 international units (24 mg) injection [1 x 24 mg cartridge] (&) inert substance diluent [1 x 3.15 mL syringe], 1 pack

10476J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1234.93	37.70	Humatrope [LY]

■ **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), 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 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, **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), 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 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, **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

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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), 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 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, **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), 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 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, **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), 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 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, **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 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

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), 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 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, **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), 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 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, **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), 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 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, **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), 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 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, **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**
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), 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 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, **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**

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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), 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 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, **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), 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 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, **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 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 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), 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 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, **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 IGF-1 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).

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), 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 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, **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 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, 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), 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 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, **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), 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 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, **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), 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 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, **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

10484T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	264.33	37.70	Omnitrope [SZ]

somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

10481P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	521.73	37.70	Omnitrope [SZ]

somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

10485W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	779.13	37.70	Omnitrope Surepal 15 [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), 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 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, **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.

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 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 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 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 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 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 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 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 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.

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; 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 commencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for commencement of treatment as a reclassified patient should be submitted.

Authority required

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Commencement 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 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 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 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 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 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 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 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 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.

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), 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 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, **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.

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), 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 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, **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.

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

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 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 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 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 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 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 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 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 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.

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; 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 commencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for commencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature associated with Turner syndrome

Treatment Phase: Commencement 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 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 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 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.

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), 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 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, **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.

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), 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 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, **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 prepubertal.

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

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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. 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), 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 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, **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.

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), 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 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, **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 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.

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), 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 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, **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.

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 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

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

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 risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **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), 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 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, **AND**

Patient must have a chronological age of less than 2 years, **AND**

Patient must have a documented clinical risk of hypoglycaemia, **AND**

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **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.

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 a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; 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

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), 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 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, **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.

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), 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 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, **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 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 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.

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), 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 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, **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.

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), 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 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, **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.

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), 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 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, **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 prepubertal.

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 18 international units (6 mg) injection [1 x 6 mg cartridge] (&) inert substance diluent [1 x 3.15 mL syringe], 1 pack

10429X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	315.81	37.70	Humatrope [LY]

somatropin 36 international units (12 mg) injection [1 x 12 mg cartridge] (&) inert substance diluent [1 x 3.15 mL syringe], 1 pack

10461N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	624.69	37.70	Humatrope [LY]

somatropin 72 international units (24 mg) injection [1 x 24 mg cartridge] (&) inert substance diluent [1 x 3.15 mL syringe], 1 pack

10502R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	1234.93	37.70	Humatrope [LY]

▪ **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

Note Special Pricing Arrangements apply.

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.

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.

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 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.

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.

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 somatotropin 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.

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.

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.

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 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 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 (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.

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**

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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 a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **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 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 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.

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), 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 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, **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 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

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), 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 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, **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.

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), 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 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, **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 IGF-1 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.

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**

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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

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

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 risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **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 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 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 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 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 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 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 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 a chronological age of less than 2 years, **AND**

Patient must have a documented clinical risk of hypoglycaemia, **AND**

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **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.

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 a documented clinical risk of hypoglycaemia; AND

4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; 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. 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), 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 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, **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.

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), 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 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, **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 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, 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.

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 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 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, **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.

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**
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), 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 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, **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.

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), 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 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, **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.

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

10432C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	335.05	37.70	Norditropin FlexPro [NO]

somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

10451C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	663.17	37.70	Norditropin FlexPro [NO]

somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

10449Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	991.29	37.70	Norditropin FlexPro [NO]

■ 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), 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 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 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 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.

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; **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 commencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for commencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Commencement 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 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 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 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 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 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 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 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 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.

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), 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 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, **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.

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), 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 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, **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.

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), 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 an adverse reaction to growth hormone; OR

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 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 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.

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; **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 commencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for commencement 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: Commencement 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 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 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 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 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 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 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 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 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.

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), 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 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, **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.

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), 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 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, **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.

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), 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 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, **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.

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. 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), 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 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, **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.

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), 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 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, **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 IGF-1 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.

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), 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 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, **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.

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 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

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

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 risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **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), 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 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, **AND**

Patient must have a chronological age of less than 2 years, **AND**

Patient must have a documented clinical risk of hypoglycaemia, **AND**

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **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.

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 a documented clinical risk of hypoglycaemia; AND

4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; 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

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), 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 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, **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.

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 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.

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), 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 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, **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 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 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.

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), 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 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, **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.

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), 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 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, **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.

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 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 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 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.

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. 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

10437H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	264.33	37.70	Norditropin SimpleXx [NO]

somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

10448X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	521.73	37.70	Norditropin SimpleXx [NO]

somatropin 30 international units (10 mg/2 mL) injection, 1 x 2 mL cartridge

10438J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	521.73	37.70	NutropinAq [IS]

somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

10470C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	779.13	37.70	Norditropin SimpleXx [NO]

■ 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

Note Special Pricing Arrangements apply.

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), 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 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, **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.

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), 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 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, **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.

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), 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 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, **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.

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), 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 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, **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.

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), 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 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, **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.

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

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), 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 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, **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.

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), 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 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, **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.

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), 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 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, **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.

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 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 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, **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.

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; **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. 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 commencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for commencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature and slow growth

Treatment Phase: Commencement 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 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 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 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 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 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, **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.

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), 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 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, **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 IGF-1 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.

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), 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 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, **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.

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 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

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

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 risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **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), 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 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, **AND**

Patient must have a chronological age of less than 2 years, **AND**

Patient must have a documented clinical risk of hypoglycaemia, **AND**

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **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.

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 a documented clinical risk of hypoglycaemia; AND

4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; 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

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), 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 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, **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.

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), 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 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, **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 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 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.

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), 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 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, **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.

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), 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 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, **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.

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 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 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 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.

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. 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

10467X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	335.05	37.70	Norditropin FlexPro [NO]

somatropin 30 international units (10 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

10496K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	663.17	37.70	Norditropin FlexPro [NO]

somatropin 45 international units (15 mg/1.5 mL) injection, 1 x 1.5 mL cartridge

10489C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	991.29	37.70	Norditropin FlexPro [NO]

▪ **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), 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 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, **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.

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), 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 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, **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.

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), 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 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, **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.

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), 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 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, **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.

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), 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 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, **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.

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

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), 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 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, **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.

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

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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), 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 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, **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.

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), 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 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, **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.

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), 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 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, **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.

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; **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. 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 commencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for commencement of treatment as a reclassified patient should be submitted.

Authority required

Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Commencement of treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and poor body composition due to Prader-Willi 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 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); 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 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 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 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 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 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 a current bone age below skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies); OR

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by a significant medical illness; OR

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

Patient must have been re-evaluated via polysomnography for airway obstruction and apnoea during the initial 32 week treatment period and any sleep disorders identified that required treatment must have been addressed, **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 developed uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height.

Population criteria:

Patient must not have a chronological age of equal to or greater than 18 years.

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, weight, and waist circumference, not older than three months); AND
4. The date at which skeletal maturity was achieved (if applicable) [Note: A bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity.]; AND
5. Confirmation that during the initial 32 week treatment period, the patient was re-evaluated via polysomnography for airway obstruction and apnoea, and any sleep disorders that were identified have been addressed; 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.

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), 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 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, **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.

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), 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 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, **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 IGF-1 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.

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), 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 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, **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.

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 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

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

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 risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **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), 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 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, **AND**

Patient must have a chronological age of less than 2 years, **AND**

Patient must have a documented clinical risk of hypoglycaemia, **AND**

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **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.

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 a documented clinical risk of hypoglycaemia; AND

4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; 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

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), 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 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, **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.

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), 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 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, **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 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 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.

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), 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 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, **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.

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), 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 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, **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.

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 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 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 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.

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. 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.

Authority required

Short stature and poor body composition due to Prader-Willi 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 and poor body composition due to Prader-Willi 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 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 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 non-compliance due to social/family problems, **AND**

Patient must have a current bone age below skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for 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 a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for 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

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for 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

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for 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

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for 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 Prader-Willi syndrome (the condition must be genetically proven); OR

Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist, **AND**

Patient must have been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment and any sleep disorders identified that required treatment must have been addressed; OR

Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with no sleep disorders identified; OR

Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified which are not of sufficient severity to require treatment; OR

Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified for which the patient is currently receiving ameliorative treatment, **AND**

Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height, **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 18 years or greater.

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) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome, OR
(b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; AND
4. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment, and any sleep disorders identified via the polysomnography that required treatment have been addressed; AND
5. Recent growth data (height and weight, not older than three months); AND
6. The date that skeletal maturity was achieved (if applicable); 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 (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1

10426R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	624.69	37.70	Genotropin GoQuick [PF]

SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1

10435F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	264.33	37.70	Genotropin GoQuick [PF]

somatropin 1.8 international units (600 microgram) injection [7 x 600 microgram syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

10477K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	223.15	37.70	Genotropin MiniQuick [PF]

somatropin 2.4 international units (800 microgram) injection [7 x 800 microgram syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

10463Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	295.22	37.70	Genotropin MiniQuick [PF]

somatropin 3 international units (1 mg) injection [7 x 1 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

10430Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	367.29	37.70	Genotropin MiniQuick [PF]

somatropin 3.6 international units (1.2 mg) injection [7 x 1.2 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

10457J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	439.36	37.70	Genotropin MiniQuick [PF]

somatropin 36 international units (12 mg) injection [1 x 12 mg cartridge] (&) inert substance diluent [1 x 1 mL cartridge], 1 pack

10444Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	624.69	37.70	Genotropin [PF]

somatropin 4.2 international units (1.4 mg) injection [7 x 1.4 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

10434E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	511.43	37.70	Genotropin MiniQuick [PF]

somatropin 4.8 international units (1.6 mg) injection [7 x 1.6 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

10498M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	583.51	37.70	Genotropin MiniQuick [PF]

somatropin 5.4 international units (1.8 mg) injection [7 x 1.8 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

10501Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	655.58	37.70	Genotropin MiniQuick [PF]

somatropin 6 international units (2 mg) injection [7 x 2 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

10472E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	727.65	37.70	Genotropin MiniQuick [PF]

■ SOMATROPIN

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.

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**

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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 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 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.

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 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

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 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.

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 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

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.

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'.

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

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.

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**

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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 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

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.

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 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 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.

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 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 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 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 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 (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.

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 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 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 a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **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 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 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.

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.

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 poor body composition due to Prader-Willi syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and poor body composition due to Prader-Willi syndrome category, **AND**

Patient must have been re-evaluated via polysomnography for airway obstruction and apnoea during the initial 32 week treatment period and any sleep disorders identified that required treatment must have been addressed, **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), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must have maintained or improved height percentile for 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), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must have maintained or improved body mass index SDS for 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), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must have maintained or improved waist circumference 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 have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must have maintained or improved waist/height ratio (waist circumference in centimetres divided by height in centimetres) 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 have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must have achieved an increase in height percentile with reference to the untreated Prader-Willi syndrome standards for 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), and have a bone age below skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must not have been on the maximum dose of 0.04mg/kg/week or greater for 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 have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must have maintained or improved body mass index while on the maximum dose of 0.04mg/kg/week or greater for 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 have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must have maintained or improved body mass index SDS for age and sex while on the maximum dose of 0.04mg/kg/week or greater for 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 have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must have maintained or improved waist circumference while on the maximum dose of 0.04mg/kg/week or greater for 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 have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must have maintained or improved waist/height ratio (waist circumference in centimetres divided by height in centimetres) while on the maximum dose of 0.04mg/kg/week for 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 have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must have maintained or improved weight SDS for age and sex while on the maximum dose of 0.04mg/kg/week or greater for 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 have a bone age at or above skeletal maturity (15.5 for males and 13.5 for females), **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 developed uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height.

Population criteria:

Patient must not have a chronological age of equal to or greater than 18 years.

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, weight and waist circumference) 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. The date at which skeletal maturity was achieved (if applicable) [Note: A bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity.]; **AND**
5. Confirmation that during the initial 32 week treatment period, the patient was re-evaluated via polysomnography for airway obstruction and apnoea, and any sleep disorders that were identified have been addressed; **AND**
6. 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.

Maintenance is defined as a value within a 5% tolerance (this allows for seasonal and other measurement variations).

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 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), 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 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, **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 167.7cm; OR

Patient must be female and must not have a height greater than or equal to 155.0cm.

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.

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 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), 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 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, **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 IGF-1 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.

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.

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

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), 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 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, **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 IGF-1 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.

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**

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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.

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

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

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 risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **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), 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 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, **AND**

Patient must have a chronological age of less than 2 years, **AND**

Patient must have a documented clinical risk of hypoglycaemia, **AND**

Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **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.

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 a documented clinical risk of hypoglycaemia; AND

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4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; **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. 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 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

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), 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 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, **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.

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.

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

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 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 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 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 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 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 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 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 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.

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.

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 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 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 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, **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.

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
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.

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 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), 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 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, **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.

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.

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 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), 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 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, **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.

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**

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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.

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 poor body composition due to Prader-Willi 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 and poor body composition due to Prader-Willi syndrome, **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), 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 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, **AND**

Patient must have a current bone age below skeletal maturity (15.5 for males and 13.5 for females); OR

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for 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 a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for 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

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for 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

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for 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

Patient must have a current bone age at or above skeletal maturity (15.5 for males and 13.5 for females) and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for 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 Prader-Willi syndrome (the condition must be genetically proven); OR

Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist, **AND**

Patient must have been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment and any sleep disorders identified that required treatment must have been addressed, **AND**

Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height, **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 18 years or greater.

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) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome, OR
(b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; AND
4. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment, and any sleep disorders identified via the polysomnography that required treatment have been addressed; 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. The date that skeletal maturity was achieved (if applicable); 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.

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

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

SOMATROPIN (Recombinant human growth hormone) Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative), 1

10431B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	624.69	37.70	Genotropin GoQuick [PF]

SOMATROPIN (Recombinant human growth hormone) Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative), 1

10443P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	264.33	37.70	Genotropin GoQuick [PF]

somatropin 1.8 international units (600 microgram) injection [7 x 600 microgram syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

10456H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	223.15	37.70	Genotropin MiniQuick [PF]

somatropin 2.4 international units (800 microgram) injection [7 x 800 microgram syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

10479M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	295.22	37.70	Genotropin MiniQuick [PF]

somatropin 3 international units (1 mg) injection [7 x 1 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

10480N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	367.29	37.70	Genotropin MiniQuick [PF]

somatropin 3.6 international units (1.2 mg) injection [7 x 1.2 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

10453E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	439.36	37.70	Genotropin MiniQuick [PF]

somatropin 36 international units (12 mg) injection [1 x 12 mg cartridge] (&) inert substance diluent [1 x 1 mL cartridge], 1 pack

10499N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	624.69	37.70	Genotropin [PF]

somatropin 4.2 international units (1.4 mg) injection [7 x 1.4 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

10488B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	511.43	37.70	Genotropin MiniQuick [PF]

somatropin 4.8 international units (1.6 mg) injection [7 x 1.6 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

10454F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	583.51	37.70	Genotropin MiniQuick [PF]

somatropin 5.4 international units (1.8 mg) injection [7 x 1.8 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

10500P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	655.58	37.70	Genotropin MiniQuick [PF]

somatropin 6 international units (2 mg) injection [7 x 2 mg syringes] (&) inert substance diluent [7 x 0.25 mL syringes], 1 pack

10428W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	727.65	37.70	Genotropin MiniQuick [PF]

IVF Treatment Program

▪ FOLLITROPIN ALFA + LUTROPIN ALFA

Authority required (STREAMLINED)

5250

Stimulation of follicular development

Clinical criteria:

Patient must have severe LH deficiency, **AND**

Patient must be considered appropriate for treatment with the combination product after titration of FSH and LH after at least one cycle of treatment, **AND**

Patient must be receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

follitropin alfa 150 units + lutropin alfa 75 units [1 vial] (&) inert substance diluent [1 vial], 1 pack

10491E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	7	..	..	*1242.85	37.70	Pergoveris [SG]

▪ LUTROPIN ALFA

Authority required (STREAMLINED)

5251

Stimulation of follicular development

Clinical criteria:

Patient must have severe LH deficiency, **AND**

Patient must be receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

lutropin alfa 75 international units injection [1 x 75 international units vial] (&) inert substance diluent [1 x 1 mL vial], 1 pack

10465T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	7	..	..	*722.19	37.70	Luveris [SG]

Repatriation Pharmaceutical Benefits Scheme

■ CALCIUM

Restricted benefit

Hyperphosphataemia

Clinical criteria:

The condition must be associated with chronic renal failure.

CALCIUM Tablet (chewable) 500 mg (as carbonate), 60

4094L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	1	..	*29.97	6.10	^a Cal-500 [PP]	^a Cal-Sup [IA]

CALCIUM Tablet 600 mg (as carbonate), 120

4142B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*24.15	6.10	CAL-600 [PP]

■ CALCIUM

Restricted benefit

Hypocalcaemia

Restricted benefit

Osteoporosis

Restricted benefit

Proven calcium malabsorption

CALCIUM Tablet (chewable) 500 mg (as carbonate), 60

4333C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*20.21	6.10	^a Cal-500 [PP]	^a Cal-Sup [IA]

CALCIUM Tablet 600 mg (as carbonate), 120

4082W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	17.28	6.10	CAL-600 [PP]

■ DICLOFENAC

Note Maximum quantity of four tubes (original + 3 repeats) in 12 months.

Authority required

Solar (actinic) keratosis

Treatment Phase: Management

Clinical criteria:

Patient must require topical drug therapy as field treatment for clinically visible and subclinical lesions where other standard treatments are inappropriate.

diclofenac sodium 3% gel, 25 g

4046Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	3	..	57.48	6.10	Solaraze 3% Gel [CS]

■ GABAPENTIN

Authority required

Refractory neuropathic pain

Clinical criteria:

The condition must be unable to be controlled by other drugs.

gabapentin 100 mg capsule, 100

4591P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	15.80	6.10	^a APO-Gabapentin [TX] ^a Neurontin [PF]	^a Gabapentin Aspen 100 [FM] ^a Nupentin 100 [AF]

gabapentin 300 mg capsule, 100

4592Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	28.39	6.10	^a Gabapentin 300 [CR] ^a Gantin [GN] ^a Neurontin [PF]	^a Gabapentin Aspen 300 [FM] ^a GenRx Gabapentin [GX] ^a Nupentin 300 [AF]

gabapentin 400 mg capsule, 100

4593R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	34.92	6.10	^a Gabapentin 400 [CR] ^a Gantin [GN] ^a Neurontin [PF]	^a Gabapentin Aspen 400 [FM] ^a GenRx Gabapentin [GX] ^a Nupentin 400 [AF]

gabapentin 600 mg tablet, 100

4594T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	49.32	6.10	^a Gabapentin Aspen 600 [FM] ^a Neurontin [PF]	^a GenRx Gabapentin [GX] ^a Nupentin Tabs [AF]

gabapentin 800 mg tablet, 100

4595W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	62.28	6.10	^a Gabapentin Aspen 800 [FM] ^a GenRx Gabapentin [GX] ^a Nupentin Tabs [AF]	^a Gantin [GN] ^a Neurontin [PF]

■ IMIQUIMOD**Authority required**

Superficial basal cell carcinoma

Treatment Phase: Primary treatment

Clinical criteria:The condition must be confirmed by a histological diagnosis, **AND**The condition must be one where other standard treatments are inappropriate, **AND**

The condition must require topical drug therapy.

imiquimod 5% cream, 12 x 250 mg sachets

4559Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	127.66	6.10	^a Aldara [IA] ^a APO-Imiquimod [TX]	^a Aldiq [QA]

■ MAGNESIUM ASPARTATE DIHYDRATE**Restricted benefit**

Hypomagnesaemia

The condition must be documented in the patient's medical records.

magnesium aspartate dihydrate 500 mg (equivalent to 37.4 mg of magnesium) tablet, 50

4321K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	16.75	6.10	Mag-Sup [PP]
			..	17.35	6.10	Magmin [BB]

■ ORLISTAT**Note** The patient should be ideally enrolled in an exercise program and be receiving supplemental vitamins.**Authority required**

Obesity

Treatment Phase: Initial treatment

Clinical criteria:

Patient must have a Body Mass Index (BMI) greater than or equal to 35 with no known co-morbidities; OR

Patient must have a BMI greater than or equal to 30 with 1 or more of the following co-morbidities;(i) diabetes;(ii) ischaemic heart disease;(iii) psychiatric conditions;(iv) hypertension, **AND**Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available), **AND**The treatment must not exceed 12 months in total from initial application, **AND**

Patient must not receive more than 1 continuous treatment in a lifetime.

The prescriber must provide the patient's initial body weight and BMI at the time of application.

Authority required

Obesity

Treatment Phase: Continuing treatment (3 to 6 months following commencement)

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug, **AND**

Patient must have reduced their initial body weight by 2.5 kg or 2.5% (whichever is the lesser) during the period 3 to 6 months following commencement of treatment with this drug, **AND**

The treatment must not exceed 12 months in total from initial application, **AND**

Patient must not receive more than 1 continuous treatment in a lifetime, **AND**

Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available).

Authority required

Obesity

Treatment Phase: Continuing treatment (6 to 12 months following commencement)

Clinical criteria:

Patient must have previously been issued with an authority prescription for this drug, **AND**

Patient must have reduced their initial body weight by 5 kg or 5% (whichever is the lesser) during the period 6 to 12 months following commencement of treatment with this drug, **AND**

The treatment must not exceed 12 months in total from initial application, **AND**

Patient must not receive more than 1 continuous treatment in a lifetime, **AND**

Patient must be receiving, or enrolled to receive, professional dietetic and weight management advice (where this is available).

orlistat 120 mg capsule, 84

4570M

Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
1	2	..	132.00	6.10	Xenical [RO]