



PB 104 of 2025

National Health (Listing of Pharmaceutical Benefits) Amendment (October Update) Instrument 2025

National Health Act 1953

I, REBECCA RICHARDSON, Assistant Secretary, PBS Listing, Pricing and Policy Branch, Technology Assessment and Access Division, Department of Health, Disability and Ageing, delegate of the Minister for Health and Ageing, make this Instrument under sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953*.

Dated 29 September 2025

REBECCA RICHARDSON

Assistant Secretary
PBS Listing, Pricing and Policy Branch
Technology Assessment and Access Division

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1. Name

- (1) This instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment (October Update) Instrument 2025*.
- (2) This Instrument may also be cited as PB 104 of 2025.

2. Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement Information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	1 October 2025	1 October 2025

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3. Authority

This instrument is made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953*.

4. Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

National Health (Listing of Pharmaceutical Benefits) Instrument 2024 (PB 26 of 2024)

[1] Schedule 1, Part 1, entries for Abacavir with lamivudine

omit:

Abacavir with lamivudine	Tablet containing abacavir 600 mg (as sulfate) with lamivudine 300 mg	Oral	Kivexa	VI	MP NP	C4527 C4528	60	5	30	D(100)
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[2] Schedule 1, Part 1, after entry for Abemaciclib in the form Tablet 150 mg

insert:

Abiraterone	Tablet containing abiraterone acetate 250 mg	Oral	Abiraterone MedTas	TN	MP	C13945	120	2	120	
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[3] Schedule 1, Part 1, after entry for Abiraterone in the form Tablet containing abiraterone acetate 500 mg [Brand: Abiraterone Dr.Reddy's]

insert:

Abiraterone	Tablet containing abiraterone acetate 500 mg	Oral	Abiraterone MedTas	TN	MP	C13945	60	2	60	
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[4] Schedule 1, Part 1, entry for Acitretin in the form Capsule 10 mg [Brand: Neotigason]

(a) *omit from the column headed "Authorised Prescriber":* MP *substitute:* MP NP

(b) *omit from the column headed "Circumstances":* C5727 C5789 *substitute:* C17272 C17316

[5] Schedule 1, Part 1, entry for Acitretin in the form Capsule 10 mg [Brand: ZETIN]

(a) *omit from the column headed "Authorised Prescriber":* MP *substitute:* MP NP

(b) *omit from the column headed "Circumstances":* C5727 C5789 *substitute:* C17272 C17316

[6] Schedule 1, Part 1, entry for Acitretin in the form Capsule 25 mg [Brand: Neotigason]

(a) *omit from the column headed "Authorised Prescriber":* MP *substitute:* MP NP

(b) *omit from the column headed "Circumstances":* C5727 C5789 *substitute:* C17272 C17316

[7] Schedule 1, Part 1, entry for Acitretin in the form Capsule 25 mg [Brand: ZETIN]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- (b) omit from the column headed "Circumstances": C5727 C5789 substitute: C17272 C17316

[8] Schedule 1, Part 1, entry for Aflibercept in the form Solution for intravitreal injection 3.6 mg in 90 microlitres (40 mg per mL) pre-filled syringe [Maximum Quantity: 1; Number of Repeats: 5]

- (a) omit from the column headed "Circumstances": C13388
- (b) insert in numerical order in the column headed "Circumstances": C17289
- (c) omit from the column headed "Purposes": P13388
- (d) insert in numerical order in the column headed "Purposes": P17289

[9] Schedule 1, Part 1, entry for Aflibercept in the form Solution for intravitreal injection 4 mg in 100 microlitres (40 mg per mL) [Maximum Quantity: 1; Number of Repeats: 5]

- (a) omit from the column headed "Circumstances": C13388
- (b) insert in numerical order in the column headed "Circumstances": C17289
- (c) omit from the column headed "Purposes": P13388
- (d) insert in numerical order in the column headed "Purposes": P17289

[10] Schedule 1, Part 1, entry for Aflibercept in the form Solution for intravitreal injection 11.43 mg in 100 microlitres (114.3 mg per mL) [Maximum Quantity: 1; Number of Repeats: 5]

- (a) omit from the column headed "Circumstances": C15919 C15928
- (b) insert in numerical order in the column headed "Circumstances": C17289
- (c) omit from the column headed "Purposes": P15919 P15928
- (d) insert in numerical order in the column headed "Purposes": P17289

[11] Schedule 1, Part 1, entries for Allopurinol in the form Tablet 100 mg

omit:

Allopurinol	Tablet 100 mg	Oral	NOUMED ALLOPURINOL	VO	MP NP		200	2	200
Allopurinol	Tablet 100 mg	Oral	NOUMED ALLOPURINOL	VO	MP NP	P14238	400	2	200

[12] Schedule 1, Part 1, after entry for Allopurinol in the form Tablet 300 mg [Brand: NOUMED ALLOPURINOL; Maximum Quantity: 120; Number of Repeats: 2]

insert:

Allopurinol	Tablet 300 mg	Oral	Progout Viatris	AL	MP NP		60	2	60
Allopurinol	Tablet 300 mg	Oral	Progout Viatris	AL	MP NP	P14238	120	2	60

[13] Schedule 1, Part 1, entries for Amlodipine in the form Tablet 5 mg (as besilate)

omit:

Amlodipine	Tablet 5 mg (as besilate)	Oral	NOUMED AMLODIPINE	VO	MP NP		30	5	30
Amlodipine	Tablet 5 mg (as besilate)	Oral	NOUMED AMLODIPINE	VO	MP NP	P14238	60	5	30

[14] Schedule 1, Part 1, entries for Amlodipine in the form Tablet 10 mg (as besilate)

omit:

Amlodipine	Tablet 10 mg (as besilate)	Oral	NOUMED AMLODIPINE	VO	MP NP		30	5	30
Amlodipine	Tablet 10 mg (as besilate)	Oral	NOUMED AMLODIPINE	VO	MP NP	P14238	60	5	30

[15] Schedule 1, Part 1, entries for Amoxicillin in the form Powder for oral suspension 125 mg (as trihydrate) per 5 mL, 100 mL

omit:

Amoxicillin	Powder for oral suspension 125 mg (as trihydrate) per 5 mL, 100 mL	Oral	NOUMED AMOXICILLIN	VO	PDP		1	0	1
Amoxicillin	Powder for oral suspension 125 mg (as trihydrate) per 5 mL, 100 mL	Oral	NOUMED AMOXICILLIN	VO	MP NP MW		1	1	1

[16] Schedule 1, Part 1, entry for Apremilast in the form Pack containing 4 tablets 10 mg, 4 tablets 20 mg and 19 tablets 30 mg

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- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- (b) omit from the column headed "Circumstances": C15326 substitute: C17351
- [17] Schedule 1, Part 1, entry for Apremilast in the form Tablet 30 mg**
- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- (b) omit from the column headed "Circumstances": C15326 substitute: C17351
- [18] Schedule 1, Part 1, entry for Atezolizumab in the form Solution concentrate for I.V. infusion 1200 mg in 20 mL**
- (a) omit from the column headed "Circumstances": C13448
- (b) insert in numerical order in the column headed "Circumstances": C17127
- [19] Schedule 1, Part 1, entry for Atezolizumab in the form Solution for subcutaneous injection 1875 mg in 15 mL [Maximum Quantity: 1; Number of Repeats: 5]**
- (a) omit from the column headed "Circumstances": C13448
- (b) insert in numerical order in the column headed "Circumstances": C17127
- (c) omit from the column headed "Purposes": P13448
- (d) insert in numerical order in the column headed "Purposes": P17127
- [20] Schedule 1, Part 1, entry for Atomoxetine in the form Capsule 10 mg (as hydrochloride) [Brand: APO-Atomoxetine]**
- omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- [21] Schedule 1, Part 1, entry for Atomoxetine in the form Capsule 10 mg (as hydrochloride) [Brand: Atomoxetine Sandoz]**
- omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- [22] Schedule 1, Part 1, entry for Atomoxetine in the form Capsule 18 mg (as hydrochloride) [Brand: APO-Atomoxetine]**
- omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- [23] Schedule 1, Part 1, entry for Atomoxetine in the form Capsule 18 mg (as hydrochloride) [Brand: Atomoxetine Sandoz]**
- omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- [24] Schedule 1, Part 1, entry for Atomoxetine in the form Capsule 25 mg (as hydrochloride) [Brand: APO-Atomoxetine]**
- omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- [25] Schedule 1, Part 1, entry for Atomoxetine in the form Capsule 25 mg (as hydrochloride) [Brand: Atomoxetine Sandoz]**
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omit from the column headed "Authorised Prescriber": MP *substitute:* MP NP

[26] Schedule 1, Part 1, entry for Atomoxetine in the form Capsule 40 mg (as hydrochloride) [Brand: APO-Atomoxetine]

omit from the column headed "Authorised Prescriber": MP *substitute:* MP NP

[27] Schedule 1, Part 1, entry for Atomoxetine in the form Capsule 40 mg (as hydrochloride) [Brand: Atomoxetine Sandoz]

omit from the column headed "Authorised Prescriber": MP *substitute:* MP NP

[28] Schedule 1, Part 1, entry for Atomoxetine in the form Capsule 60 mg (as hydrochloride) [Brand: APO-Atomoxetine]

omit from the column headed "Authorised Prescriber": MP *substitute:* MP NP

[29] Schedule 1, Part 1, entry for Atomoxetine in the form Capsule 60 mg (as hydrochloride) [Brand: Atomoxetine Sandoz]

omit from the column headed "Authorised Prescriber": MP *substitute:* MP NP

[30] Schedule 1, Part 1, entry for Atomoxetine in the form Capsule 80 mg (as hydrochloride) [Brand: APO-Atomoxetine]

omit from the column headed "Authorised Prescriber": MP *substitute:* MP NP

[31] Schedule 1, Part 1, entry for Atomoxetine in the form Capsule 80 mg (as hydrochloride) [Brand: Atomoxetine Sandoz]

omit from the column headed "Authorised Prescriber": MP *substitute:* MP NP

[32] Schedule 1, Part 1, entry for Atomoxetine in the form Capsule 100 mg (as hydrochloride) [Brand: APO-Atomoxetine]

omit from the column headed "Authorised Prescriber": MP *substitute:* MP NP

[33] Schedule 1, Part 1, entry for Atomoxetine in the form Capsule 100 mg (as hydrochloride) [Brand: Atomoxetine Sandoz]

omit from the column headed "Authorised Prescriber": MP *substitute:* MP NP

[34] Schedule 1, Part 1, after entry for Bendamustine in the form Powder for injection containing bendamustine hydrochloride 25 mg [Brand: BENDAMUSTINE EUGIA]

insert:

Bendamustine	Powder for injection containing bendamustine hydrochloride 25 mg	Injection	BENDAMUSTINE DZ HYDROCHLORIDE MEDSURGE	DZ	MP	C7943 C7944 C7972	See Note 3	See Note 3	1	D(100)
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[35] Schedule 1, Part 1, after entry for Bendamustine in the form Powder for injection containing bendamustine hydrochloride 100 mg [Brand: BENDAMUSTINE EUGIA]

insert:

Bendamustine	Powder for injection containing bendamustine hydrochloride 100 mg	Injection	BENDAMUSTINE HYDROCHLORIDE MEDSURGE	DZ	MP	C7943 C7944 C7972	See Note 3	See Note 3	1	D(100)
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[36] Schedule 1, Part 1, entry for Betaine

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

[37] Schedule 1, Part 1, entries for Bimatoprost

substitute:

Bimatoprost	Eye drops 300 micrograms per mL, 3 mL	Application to the eye	Bimatoprost Sandoz	SZ	AO MP NP		1	5	1
Bimatoprost	Eye drops 300 micrograms per mL, 3 mL	Application to the eye	Bimatoprost Sandoz	SZ	AO MP NP	P14238	2	5	1
Bimatoprost	Eye drops 300 micrograms per mL, 3 mL	Application to the eye	BIMATOPROST-WGR	WG	AO MP NP		1	5	1
Bimatoprost	Eye drops 300 micrograms per mL, 3 mL	Application to the eye	BIMATOPROST-WGR	WG	AO MP NP	P14238	2	5	1
Bimatoprost	Eye drops 300 micrograms per mL, 3 mL	Application to the eye	Bimprozt	TY	AO MP NP		1	5	1
Bimatoprost	Eye drops 300 micrograms per mL, 3 mL	Application to the eye	Bimprozt	TY	AO MP NP	P14238	2	5	1
Bimatoprost	Eye drops 300 micrograms per mL, 3 mL	Application to the eye	Bimtop	AF	AO MP NP		1	5	1
Bimatoprost	Eye drops 300 micrograms per mL, 3 mL	Application to the eye	Bimtop	AF	AO MP NP	P14238	2	5	1

Bimatoprost	Eye drops 300 micrograms per mL, 3 mL	Application to the eye	Lumigan	VE	AO MP NP			1	5	1
Bimatoprost	Eye drops 300 micrograms per mL, 3 mL	Application to the eye	Lumigan	VE	AO MP NP	P14238		2	5	1
Bimatoprost	Eye drops 300 micrograms per mL, single dose units 0.4 mL, 30	Application to the eye	Lumigan PF	VE	AO MP NP			1	5	1
Bimatoprost	Eye drops 300 micrograms per mL, single dose units 0.4 mL, 30	Application to the eye	Lumigan PF	VE	AO MP NP	P14238		2	5	1

[38] Schedule 1, Part 1, entries for Bimatoprost with timolol

substitute:

Bimatoprost with timolol	Eye drops 300 micrograms bimatoprost with timolol 5 mg (as maleate) per mL, 3 mL	Application to the eye	Ganfort 0.3/5	VE	MP NP	C4343	P4343	1	5	1
Bimatoprost with timolol	Eye drops 300 micrograms bimatoprost with timolol 5 mg (as maleate) per mL, 3 mL	Application to the eye	Ganfort 0.3/5	VE	AO	C5038	P5038	1	5	1
Bimatoprost with timolol	Eye drops 300 micrograms bimatoprost with timolol 5 mg (as maleate) per mL, 3 mL	Application to the eye	Ganfort 0.3/5	VE	AO MP NP	C15558	P15558	2	5	1
Bimatoprost with timolol	Eye drops 300 micrograms bimatoprost with timolol 5 mg (as maleate) per mL, single dose units 0.4 mL, 30	Application to the eye	GANfort PF 0.3/5	VE	MP NP	C4343	P4343	1	5	1
Bimatoprost with timolol	Eye drops 300 micrograms bimatoprost with timolol 5 mg (as maleate) per mL, single dose units 0.4 mL, 30	Application to the eye	GANfort PF 0.3/5	VE	AO	C5038	P5038	1	5	1

Bimatoprost with timolol	Eye drops 300 micrograms bimatoprost with timolol 5 mg (as maleate) per mL, single dose units 0.4 mL, 30	Application to the eye	GANfort PF 0.3/5	VE	AO MP NP	C15558	P15558	2	5	1
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[39] Schedule 1, Part 1, entries for Bisoprolol in the form Tablet containing bisoprolol fumarate 2.5 mg

omit:

Bisoprolol	Tablet containing bisoprolol fumarate 2.5 mg	Oral	NOUMED BISOPROLOL	VO	MP NP	C5324	P5324	28	5	28
Bisoprolol	Tablet containing bisoprolol fumarate 2.5 mg	Oral	NOUMED BISOPROLOL	VO	MP NP	C14251	P14251	56	5	28

[40] Schedule 1, Part 1, entries for Bisoprolol in the form Tablet containing bisoprolol fumarate 5 mg

omit:

Bisoprolol	Tablet containing bisoprolol fumarate 5 mg	Oral	NOUMED BISOPROLOL	VO	MP NP	C5324	P5324	28	5	28
Bisoprolol	Tablet containing bisoprolol fumarate 5 mg	Oral	NOUMED BISOPROLOL	VO	MP NP	C14251	P14251	56	5	28

[41] Schedule 1, Part 1, entries for Bisoprolol in the form Tablet containing bisoprolol fumarate 10 mg

omit:

Bisoprolol	Tablet containing bisoprolol fumarate 10 mg	Oral	NOUMED BISOPROLOL	VO	MP NP	C5324	P5324	28	5	28
Bisoprolol	Tablet containing bisoprolol fumarate 10 mg	Oral	NOUMED BISOPROLOL	VO	MP NP	C14251	P14251	56	5	28

[42] Schedule 1, Part 1, after entry for Bivalirudin

insert:

Bivalirudin	Powder for I.V. injection 250 mg (as trifluoroacetate)	Injection	BIVALIRUDIN MEDSURGE	DZ	MP	C4919		1	0	1
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[43] Schedule 1, Part 1, entries for Brimonidine

substitute:

Brimonidine	Eye drops containing brimonidine tartrate 1.5 mg per mL, 5 mL	Application to the eye	Alphagan P 1.5	VE	AO MP NP			1	5	1
Brimonidine	Eye drops containing brimonidine tartrate 1.5 mg per mL, 5 mL	Application to the eye	Alphagan P 1.5	VE	AO MP NP	P14238		2	5	1
Brimonidine	Eye drops containing brimonidine tartrate 2 mg per mL, 5 mL	Application to the eye	Alphagan	VE	AO MP NP			1	5	1
Brimonidine	Eye drops containing brimonidine tartrate 2 mg per mL, 5 mL	Application to the eye	Alphagan	VE	AO MP NP	P14238		2	5	1
Brimonidine	Eye drops containing brimonidine tartrate 2 mg per mL, 5 mL	Application to the eye	Enidin	VB	AO MP NP			1	5	1
Brimonidine	Eye drops containing brimonidine tartrate 2 mg per mL, 5 mL	Application to the eye	Enidin	VB	AO MP NP	P14238		2	5	1

[44] Schedule 1, Part 1, entries for Brimonidine with timolol

substitute:

Brimonidine with timolol	Eye drops containing brimonidine tartrate 2 mg with timolol 5 mg (as maleate) per mL, 5 mL	Application to the eye	Combigan	VE	MP NP	C4343	P4343	1	5	1
Brimonidine with timolol	Eye drops containing brimonidine tartrate 2 mg with timolol 5 mg (as maleate) per mL, 5 mL	Application to the eye	Combigan	VE	AO	C5038	P5038	1	5	1
Brimonidine with timolol	Eye drops containing brimonidine tartrate 2 mg with timolol 5 mg (as maleate) per mL, 5 mL	Application to the eye	Combigan	VE	AO MP NP	C15558	P15558	2	5	1

[45] Schedule 1, Part 1, entries for Brinzolamide

substitute:

Brinzolamide	Eye drops 10 mg per mL, 5 mL	Application to the eye	Azopt	NV	AO MP NP		1	5	1
Brinzolamide	Eye drops 10 mg per mL, 5 mL	Application to the eye	Azopt	NV	AO MP NP	P14238	2	5	1
Brinzolamide	Eye drops 10 mg per mL, 5 mL	Application to the eye	BrinzoQuin	NM	AO MP NP		1	5	1
Brinzolamide	Eye drops 10 mg per mL, 5 mL	Application to the eye	BrinzoQuin	NM	AO MP NP	P14238	2	5	1

[46] Schedule 1, Part 1, entry for Brinzolamide with brimonidine in the form Eye drops 10 mg brinzolamide with 2 mg brimonidine tartrate per mL, 5 mL [Authorised Prescriber: MP; Maximum Quantity: 1; Number of Repeats: 5]

- (a) omit from the column headed "Authorised Prescriber": MP *substitute:* MP NP
- (b) omit from the column headed "Circumstances": C5630 *substitute:* C4343
- (c) omit from the column headed "Purposes": P5630 *substitute:* P4343

[47] Schedule 1, Part 1, entry for Brinzolamide with brimonidine in the form Eye drops 10 mg brinzolamide with 2 mg brimonidine tartrate per mL, 5 mL [Maximum Quantity: 2; Number of Repeats: 5]

omit from the column headed "Authorised Prescriber": MP AO *substitute:* AO MP NP

[48] Schedule 1, Part 1, entry for Brinzolamide with timolol in the form Eye drops 10 mg brinzolamide with timolol 5 mg (as maleate) per mL, 5 mL [Authorised Prescriber: MP; Maximum Quantity: 1; Number of Repeats: 5]

omit from the column headed "Authorised Prescriber": MP *substitute:* MP NP

[49] Schedule 1, Part 1, entry for Brinzolamide with timolol in the form Eye drops 10 mg brinzolamide with timolol 5 mg (as maleate) per mL, 5 mL [Maximum Quantity: 2; Number of Repeats: 5]

omit from the column headed "Authorised Prescriber": MP AO *substitute:* AO MP NP

[50] Schedule 1, Part 1, entry for Budesonide in the form Tablet 500 micrograms (orally disintegrating) [Maximum Quantity: 60; Number of

Repeats: 5]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
(b) omit from the column headed "Circumstances": C14619 substitute: C17406
(c) omit from the column headed "Purposes": P14619 substitute: P17406

[51] Schedule 1, Part 1, entry for Budesonide in the form Tablet 500 micrograms (orally disintegrating) [Maximum Quantity: 60; Number of Repeats: 8]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
(b) omit from the column headed "Circumstances": C14610 substitute: C17409
(c) omit from the column headed "Purposes": P14610 substitute: P17409

[52] Schedule 1, Part 1, entry for Budesonide in the form Tablet 1 mg (orally disintegrating) [Maximum Quantity: 60; Number of Repeats: 5]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
(b) omit from the column headed "Circumstances": C14619 substitute: C17406
(c) omit from the column headed "Purposes": P14619 substitute: P17406

[53] Schedule 1, Part 1, entry for Budesonide in the form Tablet 1 mg (orally disintegrating) [Maximum Quantity: 60; Number of Repeats: 8]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
(b) omit from the column headed "Circumstances": C14610 substitute: C17409
(c) omit from the column headed "Purposes": P14610 substitute: P17409

[54] Schedule 1, Part 1, after entry for Budesonide with formoterol in the form Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 60 doses [Authorised Prescriber: MP; Maximum Quantity: 2; Number of Repeats: 5]

insert:

Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	Bufomix EASYHALER 200/6	OX	MP NP	C10464	P10464	1	2	1
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Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	Bufomix EASYHALER 200/6	OX	MP NP	C7970	P7970	1	5	1
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	Bufomix EASYHALER 200/6	OX	MP	C10538	P10538	1	5	1
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	Bufomix EASYHALER 200/6	OX	MP NP	C15680	P15680	2	5	1
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	Bufomix EASYHALER 200/6	OX	MP	C15577	P15577	2	5	1

[55] Schedule 1, Part 1, entries for Candesartan with hydrochlorothiazide in the form Tablet containing candesartan cilexetil 16 mg with hydrochlorothiazide 12.5 mg

omit:

Candesartan with hydrochlorothiazide	Tablet containing candesartan cilexetil 16 mg with hydrochlorothiazide 12.5 mg	Oral	NOUMED CANDESARTAN/HCT	VO	MP NP	C4374	P4374	30	5	30
Candesartan with	Tablet containing candesartan cilexetil 16 mg	Oral	NOUMED CANDESARTAN/	VO	MP NP	C14255	P14255	60	5	30

hydrochlorothiazide	with hydrochlorothiazide 12.5 mg	HCT
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[56] Schedule 1, Part 1, entries for Candesartan with hydrochlorothiazide in the form Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 12.5 mg

omit:

Candesartan with hydrochlorothiazide	Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 12.5 mg	Oral	NOUMED CANDESARTAN/HCT	VO	MP NP	C4374	P4374	30	5	30
Candesartan with hydrochlorothiazide	Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 12.5 mg	Oral	NOUMED CANDESARTAN/HCT	VO	MP NP	C14255	P14255	60	5	30

[57] Schedule 1, Part 1, entries for Candesartan with hydrochlorothiazide in the form Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 25 mg

omit:

Candesartan with hydrochlorothiazide	Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 25 mg	Oral	NOUMED CANDESARTAN/HCT	VO	MP NP	C4374	P4374	30	5	30
Candesartan with hydrochlorothiazide	Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 25 mg	Oral	NOUMED CANDESARTAN/HCT	VO	MP NP	C14255	P14255	60	5	30

[58] Schedule 1, Part 1, after entry for Capecitabine [Brand: Xelabine]

insert:

Capivasertib	Tablet 160 mg	Oral	Truqap	AP	MP	C17398		64	5	64
Capivasertib	Tablet 200 mg	Oral	Truqap	AP	MP	C17398		64	5	64

[59] Schedule 1, Part 1, entry for Cefalexin in the form Capsule 250 mg (as monohydrate) [Brand: APO-Cephalexin; Maximum Quantity: 40; Number of Repeats: 2]

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- omit from the column headed "Authorised Prescriber": MP* *substitute: MP NP*
- [60] Schedule 1, Part 1, entry for Cefalexin in the form Capsule 250 mg (as monohydrate) [Brand: Ibilex 250; Maximum Quantity: 40; Number of Repeats: 2]**
- omit from the column headed "Authorised Prescriber": MP* *substitute: MP NP*
- [61] Schedule 1, Part 1, entry for Cefalexin in the form Capsule 250 mg (as monohydrate) [Brand: Keflex; Maximum Quantity: 40; Number of Repeats: 2]**
- omit from the column headed "Authorised Prescriber": MP* *substitute: MP NP*
- [62] Schedule 1, Part 1, entry for Cefalexin in the form Capsule 500 mg (as monohydrate) [Brand: APO-Cephalexin; Maximum Quantity: 40; Number of Repeats: 1]**
- (a) *omit from the column headed "Authorised Prescriber": MP* *substitute: MP NP*
- (b) *omit from the column headed "Purposes": P6188* *substitute: P17381*
- (c) *omit from the column headed "Maximum Quantity": CN6188* *substitute: CN17381*
- (d) *omit from the column headed "Number of Repeats": CN6188* *substitute: CN17381*
- [63] Schedule 1, Part 1, entry for Cefalexin in the form Capsule 500 mg (as monohydrate) [Brand: Blooms The Chemist Cefalexin; Maximum Quantity: 40; Number of Repeats: 1]**
- (a) *omit from the column headed "Authorised Prescriber": MP* *substitute: MP NP*
- (b) *omit from the column headed "Purposes": P6188* *substitute: P17381*
- (c) *omit from the column headed "Maximum Quantity": CN6188* *substitute: CN17381*
- (d) *omit from the column headed "Number of Repeats": CN6188* *substitute: CN17381*
- [64] Schedule 1, Part 1, entry for Cefalexin in the form Capsule 500 mg (as monohydrate) [Brand: Cefalexin Sandoz; Maximum Quantity: 40; Number of Repeats: 1]**
- (a) *omit from the column headed "Authorised Prescriber": MP* *substitute: MP NP*
- (b) *omit from the column headed "Purposes": P6188* *substitute: P17381*
- (c) *omit from the column headed "Maximum Quantity": CN6188* *substitute: CN17381*
- (d) *omit from the column headed "Number of Repeats": CN6188* *substitute: CN17381*
- [65] Schedule 1, Part 1, entry for Cefalexin in the form Capsule 500 mg (as monohydrate) [Brand: Cephalax 500; Maximum Quantity: 40;**
-

Number of Repeats: 1]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- (b) omit from the column headed "Purposes": P6188 substitute: P17381
- (c) omit from the column headed "Maximum Quantity": CN6188 substitute: CN17381
- (d) omit from the column headed "Number of Repeats": CN6188 substitute: CN17381

[66] Schedule 1, Part 1, entry for Cefalexin in the form Capsule 500 mg (as monohydrate) [Brand: Cephalixin generichealth; Maximum Quantity: 40; Number of Repeats: 1]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- (b) omit from the column headed "Purposes": P6188 substitute: P17381
- (c) omit from the column headed "Maximum Quantity": CN6188 substitute: CN17381
- (d) omit from the column headed "Number of Repeats": CN6188 substitute: CN17381

[67] Schedule 1, Part 1, entry for Cefalexin in the form Capsule 500 mg (as monohydrate) [Brand: CEPHALEXIN-WGR; Maximum Quantity: 40; Number of Repeats: 1]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- (b) omit from the column headed "Purposes": P6188 substitute: P17381
- (c) omit from the column headed "Maximum Quantity": CN6188 substitute: CN17381
- (d) omit from the column headed "Number of Repeats": CN6188 substitute: CN17381

[68] Schedule 1, Part 1, entry for Cefalexin in the form Capsule 500 mg (as monohydrate) [Brand: Ibilex 500; Maximum Quantity: 40; Number of Repeats: 1]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- (b) omit from the column headed "Purposes": P6188 substitute: P17381
- (c) omit from the column headed "Maximum Quantity": CN6188 substitute: CN17381
- (d) omit from the column headed "Number of Repeats": CN6188 substitute: CN17381

[69] Schedule 1, Part 1, entry for Cefalexin in the form Capsule 500 mg (as monohydrate) [Brand: Keflex; Maximum Quantity: 40; Number of Repeats: 1]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP

- (b) omit from the column headed "Purposes": P6188 substitute: P17381
- (c) omit from the column headed "Maximum Quantity": CN6188 substitute: CN17381
- (d) omit from the column headed "Number of Repeats": CN6188 substitute: CN17381

[70] Schedule 1, Part 1, entries for Cefalexin in the form Capsule 500 mg (as monohydrate)

omit:

Cefalexin	Capsule 500 mg (as monohydrate)	Oral	NOUMED CEFALEXIN	VO	MP NP MW PDP		20	0	20
Cefalexin	Capsule 500 mg (as monohydrate)	Oral	NOUMED CEFALEXIN	VO	MP NP MW	P10410	40 CN1041 0	0 CN1041 0	20
Cefalexin	Capsule 500 mg (as monohydrate)	Oral	NOUMED CEFALEXIN	VO	MP	P6188	40 CN6188	1 CN6188	20

[71] Schedule 1, Part 1, entry for Cefuroxime in the form Powder for oral suspension 125 mg (as axetil) per 5 mL, 70 mL (S19A) [Maximum Quantity: 2; Number of Repeats: 1]

omit from the column headed "Authorised Prescriber": MP substitute: MP NP

[72] Schedule 1, Part 1, entry for Cefuroxime in the form Tablet 250 mg (as axetil) [Brand: Pharmacor Cefuroxime; Maximum Quantity: 20; Number of Repeats: 1]

omit from the column headed "Authorised Prescriber": MP substitute: MP NP

[73] Schedule 1, Part 1, entry for Cefuroxime in the form Tablet 250 mg (as axetil) [Brand: Zinnat; Maximum Quantity: 20; Number of Repeats: 1]

omit from the column headed "Authorised Prescriber": MP substitute: MP NP

[74] Schedule 1, Part 1, entry for Celecoxib in the form Capsule 100 mg [Brand: Celebrex]

omit from the column headed "Responsible Person": UJ substitute: GO

[75] Schedule 1, Part 1, entry for Celecoxib in the form Capsule 200 mg [Brand: Celebrex]

omit from the column headed "Responsible Person": UJ substitute: GO

[76] Schedule 1, Part 1, entries for Cemiplimab

substitute:

Cemiplimab	Solution concentrate for I.V. Injection	Libtayo	WM	MP	C13411 C13419 C15063 C17359	See Note 3	See Note 3	1	D(100)
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[77] Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 10 mg [Maximum Quantity: 120; Number of Repeats: 3]

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

[78] Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 10 mg [Maximum Quantity: 240; Number of Repeats: 3]

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

[79] Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 25 mg [Brand: APO-Ciclosporin; Maximum Quantity: 60; Number of Repeats: 3]

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

[80] Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 25 mg [Brand: APO-Ciclosporin; Maximum Quantity: 120; Number of Repeats: 3]

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

[81] Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 25 mg [Brand: CICLOSPORIN-WGR; Maximum Quantity: 60; Number of Repeats: 3]

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

[82] Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 25 mg [Brand: CICLOSPORIN-WGR; Maximum Quantity: 120; Number of Repeats: 3]

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

[83] Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 25 mg [Brand: Neoral 25; Maximum Quantity: 60; Number of Repeats: 3]

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

[84] Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 25 mg [Brand: Neoral 25; Maximum Quantity: 120; Number of Repeats: 3]

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

[85] Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 50 mg [Brand: APO-Ciclosporin; Maximum Quantity: 60; Number of

Repeats: 3]

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [86] Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 50 mg [Brand: APO-Ciclosporin; Maximum Quantity: 120; Number of Repeats: 3]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [87] Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 50 mg [Brand: CICLOSPORIN-WGR; Maximum Quantity: 60; Number of Repeats: 3]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [88] Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 50 mg [Brand: CICLOSPORIN-WGR; Maximum Quantity: 120; Number of Repeats: 3]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [89] Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 50 mg [Brand: Neoral 50; Maximum Quantity: 60; Number of Repeats: 3]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [90] Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 50 mg [Brand: Neoral 50; Maximum Quantity: 120; Number of Repeats: 3]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [91] Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 100 mg [Brand: APO-Ciclosporin; Maximum Quantity: 60; Number of Repeats: 3]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [92] Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 100 mg [Brand: APO-Ciclosporin; Maximum Quantity: 120; Number of Repeats: 3]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [93] Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 100 mg [Brand: CICLOSPORIN-WGR; Maximum Quantity: 60; Number of Repeats: 3]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [94] Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 100 mg [Brand: CICLOSPORIN-WGR; Maximum Quantity: 120; Number of Repeats: 3]**
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omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [95] **Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 100 mg [Brand: Neoral 100; Maximum Quantity: 60; Number of Repeats: 3]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [96] **Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 100 mg [Brand: Neoral 100; Maximum Quantity: 120; Number of Repeats: 3]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [97] **Schedule 1, Part 1, entry for Ciclosporin in the form Oral liquid 100 mg per mL, 50 mL [Maximum Quantity: 2; Number of Repeats: 3]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [98] **Schedule 1, Part 1, entry for Ciclosporin in the form Oral liquid 100 mg per mL, 50 mL [Maximum Quantity: 4; Number of Repeats: 3]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [99] **Schedule 1, Part 1, entry for Ciprofloxacin in the form Eye drops 3 mg (as hydrochloride) per mL, 5 mL [Brand: CiloQuin; Maximum Quantity: 2; Number of Repeats: 0]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [100] **Schedule 1, Part 1, entry for Ciprofloxacin in the form Eye drops 3 mg (as hydrochloride) per mL, 5 mL [Brand: Ciloxan; Maximum Quantity: 2; Number of Repeats: 0]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [101] **Schedule 1, Part 1, entries for Ciprofloxacin in the form Tablet 500 mg (as hydrochloride)**

omit:

Ciprofloxacin	Tablet 500 mg (as hydrochloride)	Oral	NOUMED CIPROFLOXACIN	VO	MP NP	C5614 C5615 C5687 C5688 C5689 C5722 C5780	14	0	14
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- [102] **Schedule 1, Part 1, entries for Ciprofloxacin in the form Tablet 750 mg (as hydrochloride)**

omit:

Ciprofloxacin	Tablet 750 mg (as hydrochloride)	Oral	NOUMED CIPROFLOXACIN	VO	MP NP	C5614 C5615 C5687 C5688 C5689 C5722	14	0	14
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[103] Schedule 1, Part 1, entries for Citalopram in the form Tablet 20 mg (as hydrobromide)*omit:*

Citalopram	Tablet 20 mg (as hydrobromide)	Oral	NOUMED CITALOPRAM	VO	MP NP	C4755	P4755	28	5	28
Citalopram	Tablet 20 mg (as hydrobromide)	Oral	NOUMED CITALOPRAM	VO	MP NP	C15666	P15666	56	2	28

[104] Schedule 1, Part 1, entries for Citalopram in the form Tablet 40 mg (as hydrobromide)*omit:*

Citalopram	Tablet 40 mg (as hydrobromide)	Oral	NOUMED CITALOPRAM	VO	MP NP	C4755	P4755	28	5	28
Citalopram	Tablet 40 mg (as hydrobromide)	Oral	NOUMED CITALOPRAM	VO	MP NP	C15666	P15666	56	2	28

[105] Schedule 1, Part 1, entry for Clobetasol in the form Cream containing clobetasol propionate 500 micrograms per g, 30 g*omit from the column headed "Authorised Prescriber":* MP*substitute:* MP NP**[106] Schedule 1, Part 1, entry for Clobetasol in the form Ointment containing clobetasol propionate 500 micrograms per g, 30 g***omit from the column headed "Authorised Prescriber":* MP*substitute:* MP NP**[107] Schedule 1, Part 1, entry for Clobetasol in the form Shampoo containing clobetasol propionate 500 micrograms per mL, 125 mL***(a) omit from the column headed "Authorised Prescriber":* MP*substitute:* MP NP*(b) omit from the column headed "Circumstances":* C5461*substitute:* C17270**[108] Schedule 1, Part 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 50 mg [Brand: Androcur; Maximum Quantity: 100; Number of Repeats: 5]***omit from the column headed "Authorised Prescriber":* MP*substitute:* MP NP**[109] Schedule 1, Part 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 50 mg [Brand: Androcur; Maximum Quantity: 200; Number of Repeats: 5]***omit from the column headed "Authorised Prescriber":* MP*substitute:* MP NP

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- [110] **Schedule 1, Part 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 50 mg [Brand: ANTERONE 50; Maximum Quantity: 20; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [111] **Schedule 1, Part 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 50 mg [Brand: ANTERONE 50; Maximum Quantity: 40; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [112] **Schedule 1, Part 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 50 mg [Brand: ANTERONE 50; Maximum Quantity: 100; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [113] **Schedule 1, Part 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 50 mg [Brand: ANTERONE 50; Maximum Quantity: 200; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [114] **Schedule 1, Part 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 50 mg [Brand: Cyproterone Sandoz; Maximum Quantity: 20; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [115] **Schedule 1, Part 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 50 mg [Brand: Cyproterone Sandoz; Maximum Quantity: 40; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [116] **Schedule 1, Part 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 50 mg [Brand: Cyproterone Sandoz; Maximum Quantity: 100; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [117] **Schedule 1, Part 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 50 mg [Brand: Cyproterone Sandoz; Maximum Quantity: 200; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [118] **Schedule 1, Part 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 100 mg [Brand: Androcur-100; Maximum Quantity: 50; Number of Repeats: 5]**
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- omit from the column headed "Authorised Prescriber": MP* *substitute: MP NP*
- [119] Schedule 1, Part 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 100 mg [Brand: Androcur-100; Maximum Quantity: 100; Number of Repeats: 5]**
- omit from the column headed "Authorised Prescriber": MP* *substitute: MP NP*
- [120] Schedule 1, Part 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 100 mg [Brand: ANTERONE 100; Maximum Quantity: 50; Number of Repeats: 5]**
- omit from the column headed "Authorised Prescriber": MP* *substitute: MP NP*
- [121] Schedule 1, Part 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 100 mg [Brand: ANTERONE 100; Maximum Quantity: 100; Number of Repeats: 5]**
- omit from the column headed "Authorised Prescriber": MP* *substitute: MP NP*
- [122] Schedule 1, Part 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 100 mg [Brand: Cyproterone Sandoz; Maximum Quantity: 50; Number of Repeats: 5]**
- omit from the column headed "Authorised Prescriber": MP* *substitute: MP NP*
- [123] Schedule 1, Part 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 100 mg [Brand: Cyproterone Sandoz; Maximum Quantity: 100; Number of Repeats: 5]**
- omit from the column headed "Authorised Prescriber": MP* *substitute: MP NP*
- [124] Schedule 1, Part 1, entry for Dabrafenib in the form Capsule 50 mg (as mesilate) [Maximum Quantity: 120; Number of Repeats: 5]**
- (a) *insert in numerical order in the column headed "Circumstances": C17286*
- (b) *insert in numerical order in the column headed "Purposes": P17286*
- [125] Schedule 1, Part 1, entry for Dabrafenib in the form Capsule 75 mg (as mesilate) [Maximum Quantity: 120; Number of Repeats: 5]**
- (a) *insert in numerical order in the column headed "Circumstances": C17286*
- (b) *insert in numerical order in the column headed "Purposes": P17286*
- [126] Schedule 1, Part 1, entry for Deucravacitinib**
- (a) *omit from the column headed "Authorised Prescriber": MP* *substitute: MP NP*
- (b) *omit from the column headed "Circumstances": C15406* *substitute: C17391*
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- [127] **Schedule 1, Part 1, entry for Dexamethasone in the form Intravitreal injection 700 micrograms [Maximum Quantity: 1; Number of Repeats: 1]**
(a) omit from the column headed "Circumstances": C13341
(b) insert in numerical order in the column headed "Circumstances": C17387
(c) omit from the column headed "Purposes": P13341
(d) insert in numerical order in the column headed "Purposes": P17387
- [128] **Schedule 1, Part 1, entry for Dorzolamide in the form Eye drops 20 mg (as hydrochloride) per mL, 5 mL [Brand: Trusamide; Maximum Quantity: 1; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": AO MP substitute: AO MP NP
- [129] **Schedule 1, Part 1, entry for Dorzolamide in the form Eye drops 20 mg (as hydrochloride) per mL, 5 mL [Brand: Trusamide; Maximum Quantity: 2; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": AO MP substitute: AO MP NP
- [130] **Schedule 1, Part 1, entry for Dorzolamide in the form Eye drops 20 mg (as hydrochloride) per mL, 5 mL [Brand: Trusopt; Maximum Quantity: 1; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": AO MP substitute: AO MP NP
- [131] **Schedule 1, Part 1, entry for Dorzolamide in the form Eye drops 20 mg (as hydrochloride) per mL, 5 mL [Brand: Trusopt; Maximum Quantity: 2; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": AO MP substitute: AO MP NP
- [132] **Schedule 1, Part 1, entry for Dorzolamide with timolol in the form Eye drops containing dorzolamide 20 mg (as hydrochloride) with timolol 5 mg (as maleate) per mL, 5 mL [Brand: Cosdor; Authorised Prescriber: MP; Maximum Quantity: 1; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- [133] **Schedule 1, Part 1, entry for Dorzolamide with timolol in the form Eye drops containing dorzolamide 20 mg (as hydrochloride) with timolol 5 mg (as maleate) per mL, 5 mL [Brand: Cosdor; Maximum Quantity: 2; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": AO MP substitute: AO MP NP
- [134] **Schedule 1, Part 1, entry for Dorzolamide with timolol in the form Eye drops containing dorzolamide 20 mg (as hydrochloride) with timolol 5 mg (as maleate) per mL, 5 mL [Brand: Cosopt; Authorised Prescriber: MP; Maximum Quantity: 1; Number of Repeats: 5]**
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- omit from the column headed "Authorised Prescriber": MP* *substitute: MP NP*
- [135] Schedule 1, Part 1, entry for Dorzolamide with timolol in the form Eye drops containing dorzolamide 20 mg (as hydrochloride) with timolol 5 mg (as maleate) per mL, 5 mL [Brand: Cosopt; Maximum Quantity: 2; Number of Repeats: 5]**
- omit from the column headed "Authorised Prescriber": AO MP* *substitute: AO MP NP*
- [136] Schedule 1, Part 1, entry for Dorzolamide with timolol in the form Eye drops containing dorzolamide 20 mg (as hydrochloride) with timolol 5 mg (as maleate) per mL, 5 mL [Brand: Vizo-PF Dorzolatim; Authorised Prescriber: MP; Maximum Quantity: 1; Number of Repeats: 5]**
- omit from the column headed "Authorised Prescriber": MP* *substitute: MP NP*
- [137] Schedule 1, Part 1, entry for Dorzolamide with timolol in the form Eye drops containing dorzolamide 20 mg (as hydrochloride) with timolol 5 mg (as maleate) per mL, 5 mL [Brand: Vizo-PF Dorzolatim; Maximum Quantity: 2; Number of Repeats: 5]**
- omit from the column headed "Authorised Prescriber": AO MP* *substitute: AO MP NP*
- [138] Schedule 1, Part 1, entry for Doxycycline in the form Capsule 100 mg (as hyclate) (containing enteric coated pellets) [Brand: Doryx; Maximum Quantity: 28; Number of Repeats: 5]**
- omit from the column headed "Authorised Prescriber": MP* *substitute: MP NP*
- [139] Schedule 1, Part 1, entry for Doxycycline in the form Capsule 100 mg (as hyclate) (containing enteric coated pellets) [Brand: Doryx; Maximum Quantity: 56; Number of Repeats: 2]**
- omit from the column headed "Authorised Prescriber": MP* *substitute: MP NP*
- [140] Schedule 1, Part 1, entry for Doxycycline in the form Capsule 100 mg (as hyclate) (containing enteric coated pellets) [Brand: Mayne Pharma Doxycycline; Maximum Quantity: 28; Number of Repeats: 5]**
- omit from the column headed "Authorised Prescriber": MP* *substitute: MP NP*
- [141] Schedule 1, Part 1, entry for Doxycycline in the form Capsule 100 mg (as hyclate) (containing enteric coated pellets) [Brand: Mayne Pharma Doxycycline; Maximum Quantity: 56; Number of Repeats: 2]**
- omit from the column headed "Authorised Prescriber": MP* *substitute: MP NP*
- [142] Schedule 1, Part 1, entry for Doxycycline in the form Tablet 100 mg (as hyclate) [Brand: APX-Doxycycline; Maximum Quantity: 28; Number of Repeats: 5]**
- omit from the column headed "Authorised Prescriber": MP* *substitute: MP NP*
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- [143] **Schedule 1, Part 1, entry for Doxycycline in the form Tablet 100 mg (as hyclate) [Brand: APX-Doxycycline; Maximum Quantity: 56; Number of Repeats: 2]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [144] **Schedule 1, Part 1, entry for Doxycycline in the form Tablet 100 mg (as hyclate) [Brand: Doxsig; Maximum Quantity: 28; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [145] **Schedule 1, Part 1, entry for Doxycycline in the form Tablet 100 mg (as hyclate) [Brand: Doxsig; Maximum Quantity: 56; Number of Repeats: 2]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [146] **Schedule 1, Part 1, entry for Doxycycline in the form Tablet 100 mg (as hyclate) [Brand: DOXYCYCLINE-WGR; Maximum Quantity: 28; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [147] **Schedule 1, Part 1, entry for Doxycycline in the form Tablet 100 mg (as hyclate) [Brand: DOXYCYCLINE-WGR; Maximum Quantity: 56; Number of Repeats: 2]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [148] **Schedule 1, Part 1, entry for Doxycycline in the form Tablet 100 mg (as hyclate) [Brand: Doxylin 100; Maximum Quantity: 28; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [149] **Schedule 1, Part 1, entry for Doxycycline in the form Tablet 100 mg (as hyclate) [Brand: Doxylin 100; Maximum Quantity: 56; Number of Repeats: 2]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [150] **Schedule 1, Part 1, entry for Doxycycline in the form Tablet 100 mg (as monohydrate) [Brand: Doxycycline Sandoz; Maximum Quantity: 28; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [151] **Schedule 1, Part 1, entry for Doxycycline in the form Tablet 100 mg (as monohydrate) [Brand: Doxycycline Sandoz; Maximum Quantity: 56; Number of Repeats: 2]**
-

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

[152] Schedule 1, Part 1, after entry for Duloxetine in the form Capsule 30 mg (as hydrochloride) [Brand: APO-Duloxetine]

insert:

Duloxetine	Capsule 30 mg (as hydrochloride)	Oral	Blooms The Chemist Duloxetine	BG	MP NP	C5650		28	0	28
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[153] Schedule 1, Part 1, after entry for Duloxetine in the form Capsule 60 mg (as hydrochloride) [Brand: APO-Duloxetine; Maximum Quantity: 56; Number of Repeats: 2]

insert:

Duloxetine	Capsule 60 mg (as hydrochloride)	Oral	Blooms The Chemist Duloxetine	BG	MP NP	C5650	P5650	28	5	28
Duloxetine	Capsule 60 mg (as hydrochloride)	Oral	Blooms The Chemist Duloxetine	BG	MP NP	C15553	P15553	56	2	28

[154] Schedule 1, Part 1, entry for Eletriptan in the form Tablet 40 mg (as hydrobromide)

omit from the column headed "Responsible Person": UJ substitute: GO

[155] Schedule 1, Part 1, entry for Eletriptan in the form Tablet 80 mg (as hydrobromide)

omit from the column headed "Responsible Person": UJ substitute: GO

[156] Schedule 1, Part 1, entries for Eplerenone in the form Tablet 25 mg [Brand: Inspra]

omit from the column headed "Responsible Person" (all instances): UJ substitute (all instances): GO

[157] Schedule 1, Part 1, entries for Eplerenone in the form Tablet 50 mg [Brand: Inspra]

omit from the column headed "Responsible Person" (all instances): UJ substitute (all instances): GO

[158] Schedule 1, Part 1, entry for Erythromycin in the form Capsule 250 mg (containing enteric coated pellets) [Maximum Quantity: 50; Number of Repeats: 5]

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

[159] Schedule 1, Part 1, entry for Erythromycin in the form Capsule 250 mg (containing enteric coated pellets) [Maximum Quantity: 100;

Number of Repeats: 2]

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

[160] Schedule 1, Part 1, entry for Escitalopram in the form Tablet 20 mg (as oxalate) [Brand: LoxaLate; Maximum Quantity: 28; Number of Repeats: 5]

(a) insert in numerical order in the column headed "Circumstances": C4690 C4703

(b) insert in numerical order in the column headed "Circumstances": C4756 C4757

(c) insert in numerical order in the column headed "Purposes": P4690 P4703

(d) insert in numerical order in the column headed "Purposes": P4756 P4757

[161] Schedule 1, Part 1, entry for Escitalopram in the form Tablet 20 mg (as oxalate) [Brand: LoxaLate; Maximum Quantity: 56; Number of Repeats: 2]

(a) insert in numerical order in the column headed "Circumstances": C15550 C15551

(b) insert in numerical order in the column headed "Circumstances": C15669 C15696

(c) insert in numerical order in the column headed "Purposes": P15550 P15551

(d) insert in numerical order in the column headed "Purposes": P15669 P15696

[162] Schedule 1, Part 1, after entry for Essential amino acids formula with vitamins and minerals

insert:

Estetrol with drospirenone	Pack containing 24 tablets estetrol 14.2 mg (as monohydrate) with drospirenone 3 mg and 4 inert tablets	Oral	Nextstellis	YN	MP MW NP	3	3	3
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[163] Schedule 1, Part 1, entries for Estradiol in the form Tablet containing estradiol valerate 1 mg

omit from the column headed "Responsible Person" (all instances): BN substitute (all instances): GH

[164] Schedule 1, Part 1, entries for Estradiol in the form Tablet containing estradiol valerate 2 mg

omit from the column headed "Responsible Person" (all instances): BN substitute (all instances): GH

[165] Schedule 1, Part 1, entries for Estradiol in the form Transdermal patches 585 micrograms, 8

omit:

Estradiol	Transdermal patches 585 micrograms, 8	Transdermal	Estradiol Transdermal System (Sandoz, USA)	HX	MP NP	1	5	1
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[166] Schedule 1, Part 1, entries for Estradiol in the form Transdermal patches 1.56 mg, 8

omit:

Estradiol	Transdermal patches 1.56 mg, 8	Transdermal	Estradiol Transdermal System (Sandoz, USA)	HX	MP NP	1	5	1
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[167] Schedule 1, Part 1, entries for Etanercept

substitute:

Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Brenzys	RF	MP	C9064 C14488 P9064 P14488 C14581 C14582 P14581 P14582 C14603 C14670 P14603 P14670 C14671 C14673 P14671 P14673 C14703 C16709 P14703 P16709 C16710 C16713 P16710 P16713 C16716 C16717 P16716 P16717 C16737 C16743 P16737 P16743 C16747 C16761 P16747 P16761 C16763 C16764 P16763 P16764 C16773 C16779 P16773 P16779 C16785 C16788 P16785 P16788 C17355 P17355	1	3	1	
Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Brenzys	RF	MP	C9081 C14499 P9081 P14499 C14507 C14629 P14507 P14629 C14683 C14701 P14683 P14701 C14715 C16720 P14715 P16720 C16725 C16750 P16725 P16750 C16754 C16765 P16754 P16765 C16766 C16772 P16766 P16772 C16778 C16789 P16778 P16789 C16792 C16795 P16792 P16795 C17326 C17374 P17326 P17374	1	5	1	
Etanercept	Injection 50 mg in 1 mL	Injection	Enbrel	PF	MP	C9417 C14068 See Note 3	See	See	1	C(100)

	single use auto-injector, 4					C14071 C14154 C14155 C17280			Note 3	Note 3		
Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Enbrel	PF	MP	C14508 C14509 P14508 P14509	1	1			1	
Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Enbrel	PF	MP	C9064 C9386 P9064 P9386 C12261 C14488 P12261 P14488 C14513 C14553 P14513 P14553 C14554 C14576 P14554 P14576 C14577 C14703 P14577 P14703 C16709 C16710 P16709 P16710 C16713 C16716 P16713 P16716 C16717 C16727 P16717 P16727 C16728 C16737 P16728 P16737 C16743 C16747 P16743 P16747 C16761 C16763 P16761 P16763 C16764 C16773 P16764 P16773 C16777 C16779 P16777 P16779 C16785 C16788 P16785 P16788 C17001 C17069 P17001 P17069 C17355 P17355	1	3		1		
Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Enbrel	PF	MP	C9081 C12123 P9081 P12123 C14499 C14507 P14499 P14507 C14715 C16718 P14715 P16718 C16725 C16750 P16725 P16750 C16754 C16765 P16754 P16765 C16766 C16772 P16766 P16772 C16775 C16789 P16775 P16789 C16792 C17326 P16792 P17326 C17374 P17374	1	5		1		
Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Erelzi	SZ	MP	C9417 C14068 See Note 3 C14071 C14154 C14155 C17280	See Note 3	See Note 3		1	C(100)	
Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Erelzi	SZ	MP	C14508 C14509 P14508 P14509	1	1		1		
Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Erelzi	SZ	MP	C9064 C9386 P9064 P9386 C12261 C14488 P12261 P14488 C14513 C14553 P14513 P14553 C14554 C14576 P14554 P14576 C14577 C14581 P14577 P14581	1	3		1		

						C14582 C14603 P14582 P14603 C14670 C14671 P14670 P14671 C14673 C14703 P14673 P14703 C16709 C16710 P16709 P16710 C16713 C16716 P16713 P16716 C16717 C16727 P16717 P16727 C16728 C16737 P16728 P16737 C16743 C16747 P16743 P16747 C16761 C16763 P16761 P16763 C16764 C16773 P16764 P16773 C16777 C16779 P16777 P16779 C16785 C16788 P16785 P16788 C17001 C17069 P17001 P17069 C17355 P17355				
Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Erelzi	SZ	MP	C9081 C12123 P9081 P12123 C14499 C14507 P14499 P14507 C14629 C14683 P14629 P14683 C14701 C14715 P14701 P14715 C16718 C16720 P16718 P16720 C16725 C16750 P16725 P16750 C16754 C16765 P16754 P16765 C16766 C16772 P16766 P16772 C16775 C16778 P16775 P16778 C16787 C16789 P16787 P16789 C16792 C16795 P16792 P16795 C17326 C17374 P17326 P17374	1	5	1	
Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Nepexto	GQ	MP	C9417 C14068 See Note 3 C14071 C14154 See Note 3 C14155 C17280 See Note 3	See Note 3	See Note 3	1	C(100)
Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Nepexto	GQ	MP	C14508 C14509 P14508 P14509	1	1	1	
Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Nepexto	GQ	MP	C9064 C9386 P9064 P9386 C12261 C14488 P12261 P14488 C14513 C14553 P14513 P14553 C14554 C14576 P14554 P14576 C14577 C14581 P14577 P14581 C14582 C14603 P14582 P14603 C14670 C14671 P14670 P14671 C14673 C14703 P14673 P14703 C16709 C16710 P16709 P16710 C16713 C16716 P16713 P16716	1	3	1	

						C16717 C16727 P16717 P16727 C16728 C16737 P16728 P16737 C16743 C16747 P16743 P16747 C16761 C16763 P16761 P16763 C16764 C16773 P16764 P16773 C16777 C16779 P16777 P16779 C16785 C16788 P16785 P16788 C17001 C17069 P17001 P17069 C17355 P17355					
Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Nepexto	GQ	MP	C9081 C12123 P9081 P12123 C14499 C14507 P14499 P14507 C14629 C14683 P14629 P14683 C14701 C14715 P14701 P14715 C16718 C16720 P16718 P16720 C16725 C16750 P16725 P16750 C16754 C16765 P16754 P16765 C16766 C16772 P16766 P16772 C16775 C16778 P16775 P16778 C16787 C16789 P16787 P16789 C16792 C16795 P16792 P16795 C17326 C17374 P17326 P17374	1	5		1	
Etanercept	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	Injection	Enbrel	PF	MP	C9417 C14068 See Note 3 C14071 C14154 See Note 3 C14155 C17280 See Note 3				1	C(100)
Etanercept	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	Injection	Enbrel	PF	MP	C14508 C14509 P14508 P14509	2	1		1	
Etanercept	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	Injection	Enbrel	PF	MP	C9064 C9386 P9064 P9386 C12261 C14488 P12261 P14488 C14513 C14553 P14513 P14553 C14554 C14576 P14554 P14576 C14577 C14703 P14577 P14703 C16709 C16710 P16709 P16710 C16713 C16716 P16713 P16716 C16717 C16727 P16717 P16727 C16728 C16737 P16728 P16737 C16743 C16747 P16743 P16747 C16761 C16763 P16761 P16763 C16764 C16773 P16764 P16773	2	3		1	

						C16777 C16779 P16777 P16779 C16785 C16788 P16785 P16788 C17001 C17069 P17001 P17069 C17355 P17355					
Etanercept	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	Injection	Enbrel	PF	MP	C9081 C12123 P9081 P12123 C14499 C14507 P14499 P14507 C14715 C16718 P14715 P16718 C16725 C16750 P16725 P16750 C16754 C16765 P16754 P16765 C16766 C16772 P16766 P16772 C16775 C16789 P16775 P16789 C16792 C17326 P16792 P17326 C17374 P17374	2	5		1	
Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Brenzys	RF	MP	C9064 C14488 P9064 P14488 C14581 C14582 P14581 P14582 C14603 C14670 P14603 P14670 C14671 C14673 P14671 P14673 C14703 C16709 P14703 P16709 C16710 C16713 P16710 P16713 C16716 C16717 P16716 P16717 C16737 C16743 P16737 P16743 C16747 C16761 P16747 P16761 C16763 C16764 P16763 P16764 C16773 C16779 P16773 P16779 C16785 C16788 P16785 P16788 C17355 P17355	1	3		1	
Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Brenzys	RF	MP	C9081 C14499 P9081 P14499 C14507 C14629 P14507 P14629 C14683 C14701 P14683 P14701 C14715 C16720 P14715 P16720 C16725 C16750 P16725 P16750 C16754 C16765 P16754 P16765 C16766 C16772 P16766 P16772 C16778 C16789 P16778 P16789 C16792 C16795 P16792 P16795 C17326 C17374 P17326 P17374	1	5		1	
Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Enbrel	PF	MP	C9417 C14068 See Note 3 C14071 C14154 See Note 3 C14155 C17280 See Note 3				1	C(100)
Etanercept	Injections 50 mg in 1 mL	Injection	Enbrel	PF	MP	C14508 C14509 P14508 P14509	1	1		1	

	single use pre-filled syringes, 4												
Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Enbrel	PF	MP	C9064 C9386 C12261 C14488 C14513 C14553 C14554 C14576 C14577 C14703 C16709 C16710 C16713 C16716 C16717 C16727 C16728 C16737 C16743 C16747 C16761 C16763 C16764 C16773 C16777 C16779 C16785 C16788 C17001 C17069 C17355	P9064 P9386 P12261 P14488 P14513 P14553 P14554 P14576 P14577 P14703 P16709 P16710 P16713 P16716 P16717 P16727 P16728 P16737 P16743 P16747 P16761 P16763 P16764 P16773 P16777 P16779 P16785 P16788 P17001 P17069 P17355	1	3	1			
Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Enbrel	PF	MP	C9081 C12123 C14499 C14507 C14715 C16718 C16725 C16750 C16754 C16765 C16766 C16772 C16775 C16789 C16792 C17326 C17374	P9081 P12123 P14499 P14507 P14715 P16718 P16725 P16750 P16754 P16765 P16766 P16772 P16775 P16789 P16792 P17326 P17374	1	5	1			
Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Erelzi	SZ	MP	C9417 C14068 C14071 C14154 C14155 C17280	See Note 3	See Note 3	See Note 3	1		C(100)	
Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Erelzi	SZ	MP	C14508 C14509	P14508 P14509	1	1	1			
Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Erelzi	SZ	MP	C9064 C9386 C12261 C14488 C14513 C14553 C14554 C14576 C14577 C14581 C14582 C14603 C14670 C14671	P9064 P9386 P12261 P14488 P14513 P14553 P14554 P14576 P14577 P14581 P14582 P14603 P14670 P14671	1	3	1			

Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Erelzi	SZ	MP	C14673	C14703	P14673	P14703	1	5	1
						C16709	C16710	P16709	P16710			
						C16713	C16716	P16713	P16716			
						C16717	C16727	P16717	P16727			
						C16728	C16737	P16728	P16737			
						C16743	C16747	P16743	P16747			
						C16761	C16763	P16761	P16763			
						C16764	C16773	P16764	P16773			
						C16777	C16779	P16777	P16779			
						C16785	C16788	P16785	P16788			
						C17001	C17069	P17001	P17069			
						C17355		P17355				
						C9081	C12123	P9081	P12123			
						C14499	C14507	P14499	P14507			
						C14629	C14683	P14629	P14683			
						C14701	C14715	P14701	P14715			
						C16718	C16720	P16718	P16720			
						C16725	C16750	P16725	P16750			
						C16754	C16765	P16754	P16765			
						C16766	C16772	P16766	P16772			
						C16775	C16778	P16775	P16778			
						C16787	C16789	P16787	P16789			
						C16792	C16795	P16792	P16795			
						C17326	C17374	P17326	P17374			

[168] Schedule 1, Part 1, entry for Evolocumab [Maximum Quantity: 3; Number of Repeats: 5]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- (b) omit from the column headed "Circumstances": C10388 C15432 substitute: C17313 C17402
- (c) omit from the column headed "Purposes": P10388 P15432 substitute: P17313 P17402

[169] Schedule 1, Part 1, after entry for Famotidine in the form Tablet 20 mg

insert:

Famotidine	Tablet 20 mg	Oral	Ausfam 20	RW	MP NP	P14238	120	5	60
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[170] Schedule 1, Part 1, after entry for Famotidine in the form Tablet 40 mg

insert:

Famotidine	Tablet 40 mg	Oral	Ausfam 40	RW	MP NP	P14238	60	5	30
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- [171] **Schedule 1, Part 1, entry for Faricimab in the form Solution for intravitreal injection 21 mg in 0.175 mL (120 mg per mL) pre-filled syringe [Maximum Quantity: 1; Number of Repeats: 5]**
- (a) omit from the column headed "Circumstances": C16442
 - (b) insert in numerical order in the column headed "Circumstances": C17289
 - (c) omit from the column headed "Purposes": P16442
 - (d) insert in numerical order in the column headed "Purposes": P17289
- [172] **Schedule 1, Part 1, entry for Faricimab in the form Solution for intravitreal injection 28.8 mg in 0.24 mL (120 mg per mL) [Maximum Quantity: 1; Number of Repeats: 5]**
- (a) omit from the column headed "Circumstances": C16442
 - (b) insert in numerical order in the column headed "Circumstances": C17289
 - (c) omit from the column headed "Purposes": P16442
 - (d) insert in numerical order in the column headed "Purposes": P17289
- [173] **Schedule 1, Part 1, entry for Flucloxacillin in the form Capsule 500 mg (as sodium monohydrate) [Brand: Flopen; Maximum Quantity: 48; Number of Repeats: 1]**
- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
 - (b) omit from the column headed "Circumstances": C6169 substitute: C17381
- [174] **Schedule 1, Part 1, entry for Flucloxacillin in the form Capsule 500 mg (as sodium monohydrate) [Brand: Flopen Viatrix; Maximum Quantity: 48; Number of Repeats: 1]**
- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
 - (b) omit from the column headed "Circumstances": C6169 substitute: C17381
- [175] **Schedule 1, Part 1, entry for Flucloxacillin in the form Capsule 500 mg (as sodium monohydrate) [Brand: Staphylex 500; Maximum Quantity: 48; Number of Repeats: 1]**
- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
 - (b) omit from the column headed "Circumstances": C6169 substitute: C17381

[176] Schedule 1, Part 1, entries for Fluconazole in the form Capsule 200 mg

omit:

Fluconazole	Capsule 200 mg	Oral	Fluconazole APOTEX	GX	MP NP	C5989 C6023 C6030 C15975 C15984 C16034	28	5	28
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[177] Schedule 1, Part 1, entry for Gabapentin in the form Tablet 800 mg [Brand: Neurontin]

omit from the column headed "Responsible Person": UJ substitute: GO

[178] Schedule 1, Part 1, entries for Ganirelix in the form Injection 250 micrograms (as acetate) in 0.5 mL pre-filled syringe [Brand: Orgalutran]

omit from the column headed "Responsible Person" (all instances): OQ substitute (all instances): AF

[179] Schedule 1, Part 1, entry for Guanfacine in the form Tablet 1 mg (as hydrochloride)

omit from the column headed "Authorised Prescriber": MP substitute: MP NP

[180] Schedule 1, Part 1, entry for Guanfacine in the form Tablet 2 mg (as hydrochloride)

omit from the column headed "Authorised Prescriber": MP substitute: MP NP

[181] Schedule 1, Part 1, entry for Guanfacine in the form Tablet 3 mg (as hydrochloride)

omit from the column headed "Authorised Prescriber": MP substitute: MP NP

[182] Schedule 1, Part 1, entry for Guanfacine in the form Tablet 4 mg (as hydrochloride)

omit from the column headed "Authorised Prescriber": MP substitute: MP NP

[183] Schedule 1, Part 1, entry for Imiquimod in the form Cream 50 mg per g, 2 g, 2

omit from the column headed "Authorised Prescriber": MP substitute: MP NP

[184] Schedule 1, Part 1, entry for Imiquimod in the form Cream 50 mg per g, 250 mg single use sachets, 12 [Brand: Aldara]

omit from the column headed "Authorised Prescriber": MP substitute: MP NP

[185] Schedule 1, Part 1, entry for Imiquimod in the form Cream 50 mg per g, 250 mg single use sachets, 12 [Brand: APO-Imiquimod]

omit from the column headed "Authorised Prescriber": MP substitute: MP NP

[186] Schedule 1, Part 1, entries for Infliximab in the form Powder for I.V. infusion 100 mg

substitute:

Infliximab	Powder for I.V. infusion 100 mg	Injection	Inflectra	PF	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	PB(100)
Infliximab	Powder for I.V. infusion 100 mg	Injection	Remicade	JC	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	PB(100)
Infliximab	Powder for I.V. infusion 100 mg	Injection	Renflexis	OQ	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	PB(100)

[187] Schedule 1, Part 1, after entry for Ipratropium in the form Pressurised inhalation containing ipratropium bromide monohydrate 21 micrograms per dose, 200 doses (CFC-free formulation)

insert:

Ipratropium	Pressurised inhalation containing ipratropium bromide monohydrate 21 micrograms per dose, 200 doses (CFC-free formulation)	Inhalation by mouth	Cipla Ipratropium	LR	MP NP			2	5	1	
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[188] Schedule 1, Part 1, entries for Irbesartan in the form Tablet 75 mg

omit:

Irbesartan	Tablet 75 mg	Oral	Noumed Irbesartan	VO	MP NP			30	5	30	
Irbesartan	Tablet 75 mg	Oral	Noumed Irbesartan	VO	MP NP	P14238		60	5	30	

[189] Schedule 1, Part 1, entries for Irbesartan in the form Tablet 150 mg

omit:

Irbesartan	Tablet 150 mg	Oral	Noumed Irbesartan	VO	MP NP			30	5	30	
Irbesartan	Tablet 150 mg	Oral	Noumed Irbesartan	VO	MP NP	P14238		60	5	30	

[190] Schedule 1, Part 1, entries for Irbesartan in the form Tablet 300 mg

omit:

Irbesartan	Tablet 300 mg	Oral	Noumed Irbesartan	VO	MP NP		30	5	30
Irbesartan	Tablet 300 mg	Oral	Noumed Irbesartan	VO	MP NP	P14238	60	5	30

[191] Schedule 1, Part 1, entry for Isotretinoin in the form Capsule 5 mg

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
 (b) omit from the column headed "Circumstances": C5224 substitute: C17268

[192] Schedule 1, Part 1, entry for Isotretinoin in the form Capsule 10 mg [Brand: APO-Isotretinoin]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
 (b) omit from the column headed "Circumstances": C5224 substitute: C17268

[193] Schedule 1, Part 1, entry for Isotretinoin in the form Capsule 10 mg [Brand: Dermatane]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
 (b) omit from the column headed "Circumstances": C5224 substitute: C17268

[194] Schedule 1, Part 1, entry for Isotretinoin in the form Capsule 10 mg [Brand: Isotretinoin GX]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
 (b) omit from the column headed "Circumstances": C5224 substitute: C17268

[195] Schedule 1, Part 1, entry for Isotretinoin in the form Capsule 10 mg [Brand: Isotretinoin Lupin]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
 (b) omit from the column headed "Circumstances": C5224 substitute: C17268

[196] Schedule 1, Part 1, entry for Isotretinoin in the form Capsule 10 mg [Brand: ISOTRETINOIN-WGR]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
 (b) omit from the column headed "Circumstances": C5224 substitute: C17268

[197] Schedule 1, Part 1, entry for Isotretinoin in the form Capsule 10 mg [Brand: Oratane]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP

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- (b) omit from the column headed "Circumstances": C5224 substitute: C17268
- [198] Schedule 1, Part 1, entry for Isotretinoin in the form Capsule 20 mg [Brand: APO-Isotretinoin]**
- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- (b) omit from the column headed "Circumstances": C5224 substitute: C17268
- [199] Schedule 1, Part 1, entry for Isotretinoin in the form Capsule 20 mg [Brand: Dermatane]**
- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- (b) omit from the column headed "Circumstances": C5224 substitute: C17268
- [200] Schedule 1, Part 1, entry for Isotretinoin in the form Capsule 20 mg [Brand: Isotretinoin Dr.Reddy's; Pack Quantity: 30]**
- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- (b) omit from the column headed "Circumstances": C5224 substitute: C17268
- [201] Schedule 1, Part 1, entry for Isotretinoin in the form Capsule 20 mg [Brand: Isotretinoin Dr.Reddy's; Pack Quantity: 60]**
- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- (b) omit from the column headed "Circumstances": C5224 substitute: C17268
- [202] Schedule 1, Part 1, entry for Isotretinoin in the form Capsule 20 mg [Brand: Isotretinoin GX]**
- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- (b) omit from the column headed "Circumstances": C5224 substitute: C17268
- [203] Schedule 1, Part 1, entry for Isotretinoin in the form Capsule 20 mg [Brand: Isotretinoin Lupin]**
- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- (b) omit from the column headed "Circumstances": C5224 substitute: C17268
- [204] Schedule 1, Part 1, entry for Isotretinoin in the form Capsule 20 mg [Brand: ISOTRETINOIN-WGR]**
- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- (b) omit from the column headed "Circumstances": C5224 substitute: C17268
- [205] Schedule 1, Part 1, entry for Isotretinoin in the form Capsule 20 mg [Brand: Oratane]**
- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- (b) omit from the column headed "Circumstances": C5224 substitute: C17268
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[206] Schedule 1, Part 1, entry for Isotretinoin in the form Capsule 20 mg [Brand: Pharmacor Isotretinoin]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
(b) omit from the column headed "Circumstances": C5224 substitute: C17268

[207] Schedule 1, Part 1, entry for Isotretinoin in the form Capsule 20 mg [Brand: Roaccutane]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
(b) omit from the column headed "Circumstances": C5224 substitute: C17268

[208] Schedule 1, Part 1, entry for Isotretinoin in the form Capsule 30 mg

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
(b) omit from the column headed "Circumstances": C5224 substitute: C17268

[209] Schedule 1, Part 1, entry for Isotretinoin in the form Capsule 40 mg [Brand: Dermatane]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
(b) omit from the column headed "Circumstances": C5224 substitute: C17268

[210] Schedule 1, Part 1, entry for Isotretinoin in the form Capsule 40 mg [Brand: Oratane]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
(b) omit from the column headed "Circumstances": C5224 substitute: C17268

[211] Schedule 1, Part 1, entries for Lamivudine in the form Tablet 150 mg

omit:

Lamivudine	Tablet 150 mg	Oral	Lamivudine Alphapharm	AF	MP NP	C4454 C4512	120	5	60	D(100)
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[212] Schedule 1, Part 1, entry for Latanoprost in the form Eye drops 50 micrograms per mL, 2.5 mL [Brand: APO-Latanoprost; Maximum Quantity: 1; Number of Repeats: 5]

omit from the column headed "Authorised Prescriber": MP AO substitute: AO MP NP

[213] Schedule 1, Part 1, entry for Latanoprost in the form Eye drops 50 micrograms per mL, 2.5 mL [Brand: APO-Latanoprost; Maximum Quantity: 2; Number of Repeats: 5]

omit from the column headed "Authorised Prescriber": MP AO substitute: AO MP NP

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- [214] **Schedule 1, Part 1, entry for Latanoprost in the form Eye drops 50 micrograms per mL, 2.5 mL [Brand: Latanoprost Sandoz; Maximum Quantity: 1; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP AO substitute: AO MP NP
- [215] **Schedule 1, Part 1, entry for Latanoprost in the form Eye drops 50 micrograms per mL, 2.5 mL [Brand: Latanoprost Sandoz; Maximum Quantity: 2; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP AO substitute: AO MP NP
- [216] **Schedule 1, Part 1, entry for Latanoprost in the form Eye drops 50 micrograms per mL, 2.5 mL [Brand: LATANOPROST-WGR; Maximum Quantity: 1; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP AO substitute: AO MP NP
- [217] **Schedule 1, Part 1, entry for Latanoprost in the form Eye drops 50 micrograms per mL, 2.5 mL [Brand: LATANOPROST-WGR; Maximum Quantity: 2; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP AO substitute: AO MP NP
- [218] **Schedule 1, Part 1, entry for Latanoprost in the form Eye drops 50 micrograms per mL, 2.5 mL [Brand: Xalaprost; Maximum Quantity: 1; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP AO substitute: AO MP NP
- [219] **Schedule 1, Part 1, entry for Latanoprost in the form Eye drops 50 micrograms per mL, 2.5 mL [Brand: Xalaprost; Maximum Quantity: 2; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP AO substitute: AO MP NP
- [220] **Schedule 1, Part 1, entry for Latanoprost in the form Eye drops 50 micrograms per mL, 2.5 mL [Brand: Xalatan; Maximum Quantity: 1; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP AO substitute: AO MP NP
- [221] **Schedule 1, Part 1, entry for Latanoprost in the form Eye drops 50 micrograms per mL, 2.5 mL [Brand: Xalatan; Maximum Quantity: 2; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP AO substitute: AO MP NP
- [222] **Schedule 1, Part 1, entry for Latanoprost with timolol in the form Eye drops 50 micrograms latanoprost with timolol 5 mg (as maleate) per mL, 2.5 mL [Brand: APO-Latanoprost/Timolol 0.05/5; Authorised Prescriber: MP; Maximum Quantity: 1; Number of Repeats: 5]**
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	<i>omit from the column headed "Authorised Prescriber":</i> MP	<i>substitute:</i> MP NP
[223]	Schedule 1, Part 1, entry for Latanoprost with timolol in the form Eye drops 50 micrograms latanoprost with timolol 5 mg (as maleate) per mL, 2.5 mL [Brand: APO-Latanoprost/Timolol 0.05/5; Maximum Quantity: 2; Number of Repeats: 5]	
	<i>omit from the column headed "Authorised Prescriber":</i> MP AO	<i>substitute:</i> AO MP NP
[224]	Schedule 1, Part 1, entry for Latanoprost with timolol in the form Eye drops 50 micrograms latanoprost with timolol 5 mg (as maleate) per mL, 2.5 mL [Brand: Xalacom; Authorised Prescriber: MP; Maximum Quantity: 1; Number of Repeats: 5]	
	<i>omit from the column headed "Authorised Prescriber":</i> MP	<i>substitute:</i> MP NP
[225]	Schedule 1, Part 1, entry for Latanoprost with timolol in the form Eye drops 50 micrograms latanoprost with timolol 5 mg (as maleate) per mL, 2.5 mL [Brand: Xalacom; Maximum Quantity: 2; Number of Repeats: 5]	
	<i>omit from the column headed "Authorised Prescriber":</i> MP AO	<i>substitute:</i> AO MP NP
[226]	Schedule 1, Part 1, entry for Latanoprost with timolol in the form Eye drops 50 micrograms latanoprost with timolol 5 mg (as maleate) per mL, 2.5 mL [Brand: Xalamol 50/5; Authorised Prescriber: MP; Maximum Quantity: 1; Number of Repeats: 5]	
	<i>omit from the column headed "Authorised Prescriber":</i> MP	<i>substitute:</i> MP NP
[227]	Schedule 1, Part 1, entry for Latanoprost with timolol in the form Eye drops 50 micrograms latanoprost with timolol 5 mg (as maleate) per mL, 2.5 mL [Brand: Xalamol 50/5; Maximum Quantity: 2; Number of Repeats: 5]	
	<i>omit from the column headed "Authorised Prescriber":</i> MP AO	<i>substitute:</i> AO MP NP
[228]	Schedule 1, Part 1, entry for Leflunomide in the form Tablet 10 mg [Brand: APO-LEFLUNOMIDE; Maximum Quantity: 30; Number of Repeats: 5]	
	<i>omit from the column headed "Authorised Prescriber":</i> MP	<i>substitute:</i> MP NP
[229]	Schedule 1, Part 1, entry for Leflunomide in the form Tablet 10 mg [Brand: APO-LEFLUNOMIDE; Maximum Quantity: 60; Number of Repeats: 5]	
	<i>omit from the column headed "Authorised Prescriber":</i> MP	<i>substitute:</i> MP NP
[230]	Schedule 1, Part 1, entry for Leflunomide in the form Tablet 10 mg [Brand: Arava; Maximum Quantity: 30; Number of Repeats: 5]	
	<i>omit from the column headed "Authorised Prescriber":</i> MP	<i>substitute:</i> MP NP
[231]	Schedule 1, Part 1, entry for Leflunomide in the form Tablet 10 mg [Brand: Arava; Maximum Quantity: 60; Number of Repeats: 5]	
	<i>omit from the column headed "Authorised Prescriber":</i> MP	<i>substitute:</i> MP NP

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- [232] **Schedule 1, Part 1, entry for Leflunomide in the form Tablet 10 mg [Brand: Ataris 10; Maximum Quantity: 30; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [233] **Schedule 1, Part 1, entry for Leflunomide in the form Tablet 10 mg [Brand: Ataris 10; Maximum Quantity: 60; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [234] **Schedule 1, Part 1, entry for Leflunomide in the form Tablet 10 mg [Brand: Leflunomide generichealth; Maximum Quantity: 30; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [235] **Schedule 1, Part 1, entry for Leflunomide in the form Tablet 10 mg [Brand: Leflunomide generichealth; Maximum Quantity: 60; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [236] **Schedule 1, Part 1, entry for Leflunomide in the form Tablet 10 mg [Brand: Leflunomide Sandoz; Maximum Quantity: 30; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [237] **Schedule 1, Part 1, entry for Leflunomide in the form Tablet 10 mg [Brand: Leflunomide Sandoz; Maximum Quantity: 60; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [238] **Schedule 1, Part 1, entry for Leflunomide in the form Tablet 10 mg [Brand: LEFLUNOMIDE-WGR; Maximum Quantity: 30; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [239] **Schedule 1, Part 1, entry for Leflunomide in the form Tablet 10 mg [Brand: LEFLUNOMIDE-WGR; Maximum Quantity: 60; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [240] **Schedule 1, Part 1, entry for Leflunomide in the form Tablet 10 mg [Brand: Lunava 10; Maximum Quantity: 30; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [241] **Schedule 1, Part 1, entry for Leflunomide in the form Tablet 10 mg [Brand: Lunava 10; Maximum Quantity: 60; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
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- [242] **Schedule 1, Part 1, entry for Leflunomide in the form Tablet 20 mg [Brand: APO-LEFLUNOMIDE; Maximum Quantity: 30; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- [243] **Schedule 1, Part 1, entry for Leflunomide in the form Tablet 20 mg [Brand: APO-LEFLUNOMIDE; Maximum Quantity: 60; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- [244] **Schedule 1, Part 1, entry for Leflunomide in the form Tablet 20 mg [Brand: Arava; Maximum Quantity: 30; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- [245] **Schedule 1, Part 1, entry for Leflunomide in the form Tablet 20 mg [Brand: Arava; Maximum Quantity: 60; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- [246] **Schedule 1, Part 1, entry for Leflunomide in the form Tablet 20 mg [Brand: Ataris 20; Maximum Quantity: 30; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- [247] **Schedule 1, Part 1, entry for Leflunomide in the form Tablet 20 mg [Brand: Ataris 20; Maximum Quantity: 60; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- [248] **Schedule 1, Part 1, entry for Leflunomide in the form Tablet 20 mg [Brand: Leflunomide generichealth; Maximum Quantity: 30; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- [249] **Schedule 1, Part 1, entry for Leflunomide in the form Tablet 20 mg [Brand: Leflunomide generichealth; Maximum Quantity: 60; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- [250] **Schedule 1, Part 1, entry for Leflunomide in the form Tablet 20 mg [Brand: Leflunomide Sandoz; Maximum Quantity: 30; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- [251] **Schedule 1, Part 1, entry for Leflunomide in the form Tablet 20 mg [Brand: Leflunomide Sandoz; Maximum Quantity: 60; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP substitute: MP NP
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- [252] Schedule 1, Part 1, entry for Leflunomide in the form Tablet 20 mg [Brand: LEFLUNOMIDE-WGR; Maximum Quantity: 30; Number of Repeats: 5]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [253] Schedule 1, Part 1, entry for Leflunomide in the form Tablet 20 mg [Brand: LEFLUNOMIDE-WGR; Maximum Quantity: 60; Number of Repeats: 5]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [254] Schedule 1, Part 1, entry for Leflunomide in the form Tablet 20 mg [Brand: Lunava 20; Maximum Quantity: 30; Number of Repeats: 5]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [255] Schedule 1, Part 1, entry for Leflunomide in the form Tablet 20 mg [Brand: Lunava 20; Maximum Quantity: 60; Number of Repeats: 5]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [256] Schedule 1, Part 1, after entry for Levetiracetam in the form Tablet 500 mg [Brand: Levetiracetam SZ; Maximum Quantity: 120; Number of Repeats: 5]**

insert:

Levetiracetam	Tablet 500 mg	Oral	Levetiracetam Viatris	MQ	MP NP	C16582	P16582	60	5	60
Levetiracetam	Tablet 500 mg	Oral	Levetiracetam Viatris	MQ	MP NP	C16615	P16615	120	5	60

- [257] Schedule 1, Part 1, after entry for Lumacaftor with ivacaftor in the form Tablet containing lumacaftor 200 mg with ivacaftor 125 mg**

insert:

Lumasiran	Solution for subcutaneous injection 94.5 mg (as sodium) in 0.5 mL	Injection	Oxlumo	WM	MP NP	C17378	C17399	P17378	P17399	5	1	1
Lumasiran	Solution for subcutaneous injection 94.5 mg (as sodium) in 0.5 mL	Injection	Oxlumo	WM	MP NP	C17401		P17401		5	2	1

- [258] Schedule 1, Part 1, entry for Medroxyprogesterone in the form Tablet containing medroxyprogesterone acetate 10 mg [Brand: Provera; Maximum Quantity: 100; Number of Repeats: 2]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [259] Schedule 1, Part 1, entry for Medroxyprogesterone in the form Tablet containing medroxyprogesterone acetate 10 mg [Brand: Provera; Maximum Quantity: 200; Number of Repeats: 2]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [260] Schedule 1, Part 1, entry for Medroxyprogesterone in the form Tablet containing medroxyprogesterone acetate 10 mg [Brand: Ralovera; Maximum Quantity: 100; Number of Repeats: 2]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [261] Schedule 1, Part 1, entry for Medroxyprogesterone in the form Tablet containing medroxyprogesterone acetate 10 mg [Brand: Ralovera; Maximum Quantity: 200; Number of Repeats: 2]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [262] Schedule 1, Part 1, entry for Mercaptopurine in the form Oral suspension containing mercaptopurine monohydrate 20 mg per mL, 100 mL**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [263] Schedule 1, Part 1, entry for Mercaptopurine in the form Tablet containing mercaptopurine monohydrate 50 mg [Brand: MERCAPTOPURINE-LINK]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [264] Schedule 1, Part 1, entry for Mercaptopurine in the form Tablet containing mercaptopurine monohydrate 50 mg [Brand: Purinethol]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [265] Schedule 1, Part 1, after entry for Mesalazine in the form Tablet 1.2 g (prolonged release) [Brand: Mezavant; Maximum Quantity: 240; Number of Repeats: 5]**

insert:

Mesalazine	Tablet 1.2 g (prolonged release)	Oral	MEZTAS	TN	MP NP	C16552	P16552	120	5	60
Mesalazine	Tablet 1.2 g (prolonged release)	Oral	MEZTAS	TN	MP NP	C16491	P16491	240	5	60

- [266] Schedule 1, Part 1, after entry for Metformin in the form Tablet (extended release) containing metformin hydrochloride 500 mg [Brand:**
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Metex XR; Maximum Quantity: 240; Number of Repeats: 5]

insert:

Metformin	Tablet (extended release) containing metformin hydrochloride 500 mg	Oral	Metformin Lupin XR	GQ	MP MW NP	C16261	P16261	120	5	120
Metformin	Tablet (extended release) containing metformin hydrochloride 500 mg	Oral	Metformin Lupin XR	GQ	MP NP	C14238	P14238	240	5	120

[267] Schedule 1, Part 1, after entry for Metformin in the form Tablet (extended release) containing metformin hydrochloride 1 g [Brand: METEX XR; Maximum Quantity: 120; Number of Repeats: 5]

insert:

Metformin	Tablet (extended release) containing metformin hydrochloride 1 g	Oral	Metformin Lupin XR	GQ	MP MW NP	C16261	P16261	60	5	60
Metformin	Tablet (extended release) containing metformin hydrochloride 1 g	Oral	Metformin Lupin XR	GQ	MP NP	C14238	P14238	120	5	60

[268] Schedule 1, Part 1, entries for Methotrexate in the form Injection 7.5 mg in 0.15 mL pre-filled syringe

substitute:

Methotrexate	Injection 7.5 mg in 0.15 mL pre-filled syringe	Injection	Trexject	LM	MP NP	C7488 C7518 C15068		4	5	1
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[269] Schedule 1, Part 1, entries for Methotrexate in the form Injection 10 mg in 0.2 mL pre-filled syringe

substitute:

Methotrexate	Injection 10 mg in 0.2 mL pre-filled syringe	Injection	Trexject	LM	MP NP	C7488 C7518 C15068		4	5	1
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[270] Schedule 1, Part 1, entries for Methotrexate in the form Injection 15 mg in 0.3 mL pre-filled syringe

substitute:

Methotrexate	Injection 15 mg in 0.3 mL	Injection	Trexject	LM	MP	C7488 C7518		4	5	1
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pre-filled syringe	NP	C15068
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[271] Schedule 1, Part 1, entries for Methotrexate in the form Injection 20 mg in 0.4 mL pre-filled syringe

substitute:

Methotrexate	Injection 20 mg in 0.4 mL pre-filled syringe	Injection	Trexject	LM	MP NP	C7488 C7518 C15068	4	5	1
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[272] Schedule 1, Part 1, entries for Methotrexate in the form Injection 25 mg in 0.5 mL pre-filled syringe

substitute:

Methotrexate	Injection 25 mg in 0.5 mL pre-filled syringe	Injection	Trexject	LM	MP NP	C7488 C7518 C15068	4	5	1
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[273] Schedule 1, Part 1, entry for Methoxyflurane

omit from the column headed "Section 100/ Prescriber Bag only": D(MP) substitute: D(MP) D(NP)

[274] Schedule 1, Part 1, entries for Montelukast in the form Tablet, chewable, 4 mg (as sodium)

omit:

Montelukast	Tablet, chewable, 4 mg (as sodium)	Oral	Montelukast APOTEX	GX	MP NP	C6666	P6666	28	5	28
Montelukast	Tablet, chewable, 4 mg (as sodium)	Oral	Montelukast APOTEX	GX	MP NP	C15642	P15642	56	5	28

[275] Schedule 1, Part 1, entries for Montelukast in the form Tablet, chewable, 5 mg (as sodium)

omit:

Montelukast	Tablet, chewable, 5 mg (as sodium)	Oral	Montelukast APOTEX	GX	MP NP	C6674 C7781	P6674 P7781	28	5	28
Montelukast	Tablet, chewable, 5 mg (as sodium)	Oral	Montelukast APOTEX	GX	MP NP	C15643 C15644	P15643 P15644	56	5	28

[276] Schedule 1, Part 1, entries for Morphine

omit:

Morphine	Oral solution containing morphine sulfate 10 mg per 5 mL in 100 mL bottle, 1 mL (S19A)	Oral	Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL	LM	MP NP	C10764 C10777	P10764 P10777	200	0	V10764 V10777	100
Morphine	Oral solution containing morphine sulfate 10 mg per 5 mL in 100 mL bottle, 1 mL (S19A)	Oral	Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL	LM	PDP	C10859	P10859	200	0		100
Morphine	Oral solution containing morphine sulfate 10 mg per 5 mL in 100 mL bottle, 1 mL (S19A)	Oral	Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL	LM	MP NP	C11697	P11697	1000	1	V11697	100
Morphine	Oral solution containing morphine sulfate 10 mg per 5 mL in 300 mL bottle, 1 mL (S19A)	Oral	Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL	LM	PDP	C10859	P10859	200	0		300
Morphine	Oral solution containing morphine sulfate 10 mg per 5 mL in 300 mL bottle, 1 mL (S19A)	Oral	Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL	LM	MP NP	C10764 C10777	P10764 P10777	200	0	V10764 V10777	300
Morphine	Oral solution containing morphine sulfate 10 mg per 5 mL in 300 mL bottle, 1 mL (S19A)	Oral	Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL	LM	MP NP	C11697	P11697	2100	1	V11697	300

[277] Schedule 1, Part 1, entry for Mycophenolic acid in the form Capsule containing mycophenolate mofetil 250 mg [Brand: APO-Mycophenolate; Maximum Quantity: 300; Number of Repeats: 5]

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

[278] Schedule 1, Part 1, entry for Mycophenolic acid in the form Capsule containing mycophenolate mofetil 250 mg [Brand: APO-Mycophenolate; Maximum Quantity: 600; Number of Repeats: 5]

	<i>omit from the column headed "Authorised Prescriber":</i> MP	<i>substitute:</i> MP NP
[279]	Schedule 1, Part 1, entry for Mycophenolic acid in the form Capsule containing mycophenolate mofetil 250 mg [Brand: Mycophenolate Sandoz; Maximum Quantity: 300; Number of Repeats: 5]	
	<i>omit from the column headed "Authorised Prescriber":</i> MP	<i>substitute:</i> MP NP
[280]	Schedule 1, Part 1, entry for Mycophenolic acid in the form Capsule containing mycophenolate mofetil 250 mg [Brand: Mycophenolate Sandoz; Maximum Quantity: 600; Number of Repeats: 5]	
	<i>omit from the column headed "Authorised Prescriber":</i> MP	<i>substitute:</i> MP NP
[281]	Schedule 1, Part 1, entry for Mycophenolic acid in the form Capsule containing mycophenolate mofetil 250 mg [Brand: Pharmacor Mycophenolate 250; Maximum Quantity: 300; Number of Repeats: 5]	
	<i>omit from the column headed "Authorised Prescriber":</i> MP	<i>substitute:</i> MP NP
[282]	Schedule 1, Part 1, entry for Mycophenolic acid in the form Capsule containing mycophenolate mofetil 250 mg [Brand: Pharmacor Mycophenolate 250; Maximum Quantity: 600; Number of Repeats: 5]	
	<i>omit from the column headed "Authorised Prescriber":</i> MP	<i>substitute:</i> MP NP
[283]	Schedule 1, Part 1, entry for Mycophenolic acid in the form Powder for oral suspension containing mycophenolate mofetil 1 g per 5 mL, 165 mL [Brand: CellCept; Maximum Quantity: 1; Number of Repeats: 5]	
	<i>omit from the column headed "Authorised Prescriber":</i> MP	<i>substitute:</i> MP NP
[284]	Schedule 1, Part 1, entry for Mycophenolic acid in the form Powder for oral suspension containing mycophenolate mofetil 1 g per 5 mL, 165 mL [Brand: CellCept; Maximum Quantity: 2; Number of Repeats: 5]	
	<i>omit from the column headed "Authorised Prescriber":</i> MP	<i>substitute:</i> MP NP
[285]	Schedule 1, Part 1, entry for Mycophenolic acid in the form Powder for oral suspension containing mycophenolate mofetil 1 g per 5 mL, 165 mL [Brand: Pharmacor Mycophenolate; Maximum Quantity: 1; Number of Repeats: 5]	
	<i>omit from the column headed "Authorised Prescriber":</i> MP	<i>substitute:</i> MP NP
[286]	Schedule 1, Part 1, entry for Mycophenolic acid in the form Powder for oral suspension containing mycophenolate mofetil 1 g per 5 mL, 165 mL [Brand: Pharmacor Mycophenolate; Maximum Quantity: 2; Number of Repeats: 5]	
	<i>omit from the column headed "Authorised Prescriber":</i> MP	<i>substitute:</i> MP NP
[287]	Schedule 1, Part 1, entry for Mycophenolic acid in the form Tablet (enteric coated) containing mycophenolate sodium equivalent to	

180 mg mycophenolic acid [Brand: Mycophenolic Acid ARX; Maximum Quantity: 120; Number of Repeats: 5]

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [288] Schedule 1, Part 1, entry for Mycophenolic acid in the form Tablet (enteric coated) containing mycophenolate sodium equivalent to 180 mg mycophenolic acid [Brand: Mycophenolic Acid ARX; Maximum Quantity: 240; Number of Repeats: 5]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [289] Schedule 1, Part 1, entry for Mycophenolic acid in the form Tablet (enteric coated) containing mycophenolate sodium equivalent to 180 mg mycophenolic acid [Brand: Myfortic; Maximum Quantity: 120; Number of Repeats: 5]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [290] Schedule 1, Part 1, entry for Mycophenolic acid in the form Tablet (enteric coated) containing mycophenolate sodium equivalent to 180 mg mycophenolic acid [Brand: Myfortic; Maximum Quantity: 240; Number of Repeats: 5]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [291] Schedule 1, Part 1, entry for Mycophenolic acid in the form Tablet (enteric coated) containing mycophenolate sodium equivalent to 360 mg mycophenolic acid [Brand: Mycophenolic Acid ARX; Maximum Quantity: 120; Number of Repeats: 5]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [292] Schedule 1, Part 1, entry for Mycophenolic acid in the form Tablet (enteric coated) containing mycophenolate sodium equivalent to 360 mg mycophenolic acid [Brand: Mycophenolic Acid ARX; Maximum Quantity: 240; Number of Repeats: 5]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [293] Schedule 1, Part 1, entry for Mycophenolic acid in the form Tablet (enteric coated) containing mycophenolate sodium equivalent to 360 mg mycophenolic acid [Brand: MYCOTEX; Maximum Quantity: 120; Number of Repeats: 5]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [294] Schedule 1, Part 1, entry for Mycophenolic acid in the form Tablet (enteric coated) containing mycophenolate sodium equivalent to 360 mg mycophenolic acid [Brand: MYCOTEX; Maximum Quantity: 240; Number of Repeats: 5]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [295] Schedule 1, Part 1, entry for Mycophenolic acid in the form Tablet (enteric coated) containing mycophenolate sodium equivalent to 360 mg mycophenolic acid [Brand: Myfortic; Maximum Quantity: 120; Number of Repeats: 5]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

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- [296] **Schedule 1, Part 1, entry for Mycophenolic acid in the form Tablet (enteric coated) containing mycophenolate sodium equivalent to 360 mg mycophenolic acid [Brand: Myfortic; Maximum Quantity: 240; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- [297] **Schedule 1, Part 1, entry for Mycophenolic acid in the form Tablet containing mycophenolate mofetil 500 mg [Brand: ARX-MYCOPHENOLATE; Maximum Quantity: 150; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- [298] **Schedule 1, Part 1, entry for Mycophenolic acid in the form Tablet containing mycophenolate mofetil 500 mg [Brand: ARX-MYCOPHENOLATE; Maximum Quantity: 300; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- [299] **Schedule 1, Part 1, entry for Mycophenolic acid in the form Tablet containing mycophenolate mofetil 500 mg [Brand: Ceptolate; Maximum Quantity: 150; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- [300] **Schedule 1, Part 1, entry for Mycophenolic acid in the form Tablet containing mycophenolate mofetil 500 mg [Brand: Ceptolate; Maximum Quantity: 300; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- [301] **Schedule 1, Part 1, entry for Mycophenolic acid in the form Tablet containing mycophenolate mofetil 500 mg [Brand: Mycophenolate GH; Maximum Quantity: 150; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- [302] **Schedule 1, Part 1, entry for Mycophenolic acid in the form Tablet containing mycophenolate mofetil 500 mg [Brand: Mycophenolate GH; Maximum Quantity: 300; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- [303] **Schedule 1, Part 1, entry for Mycophenolic acid in the form Tablet containing mycophenolate mofetil 500 mg [Brand: Mycophenolate Sandoz; Maximum Quantity: 150; Number of Repeats: 5]**
omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- [304] **Schedule 1, Part 1, entry for Mycophenolic acid in the form Tablet containing mycophenolate mofetil 500 mg [Brand: Mycophenolate Sandoz; Maximum Quantity: 300; Number of Repeats: 5]**
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omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [305] Schedule 1, Part 1, entry for Mycophenolic acid in the form Tablet containing mycophenolate mofetil 500 mg [Brand: Pharmacor Mycophenolate 500; Maximum Quantity: 150; Number of Repeats: 5]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [306] Schedule 1, Part 1, entry for Mycophenolic acid in the form Tablet containing mycophenolate mofetil 500 mg [Brand: Pharmacor Mycophenolate 500; Maximum Quantity: 300; Number of Repeats: 5]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [307] Schedule 1, Part 1, after entry for Nebivolol in the form Tablet 1.25 mg (as hydrochloride) [Brand: Nebivolol Sandoz; Maximum Quantity: 112; Number of Repeats: 5]**

insert:

Nebivolol	Tablet 1.25 mg (as hydrochloride)	Oral	NEBIVOLOL-WGR	WG	MP NP	C5324	P5324	56	5	28
Nebivolol	Tablet 1.25 mg (as hydrochloride)	Oral	NEBIVOLOL-WGR	WG	MP NP	C14251	P14251	112	5	28

- [308] Schedule 1, Part 1, after entry for Nebivolol in the form Tablet 5 mg (as hydrochloride) [Brand: Nebivolol Sandoz; Maximum Quantity: 56; Number of Repeats: 5]**

insert:

Nebivolol	Tablet 5 mg (as hydrochloride)	Oral	NEBIVOLOL-WGR	WG	MP NP	C5324	P5324	28	5	28
Nebivolol	Tablet 5 mg (as hydrochloride)	Oral	NEBIVOLOL-WGR	WG	MP NP	C14251	P14251	56	5	28

- [309] Schedule 1, Part 1, after entry for Nebivolol in the form Tablet 10 mg (as hydrochloride) [Brand: Nebivolol Sandoz; Maximum Quantity: 56; Number of Repeats: 5]**

insert:

Nebivolol	Tablet 10 mg (as hydrochloride)	Oral	NEBIVOLOL-WGR	WG	MP NP	C5324	P5324	28	5	28
Nebivolol	Tablet 10 mg (as hydrochloride)	Oral	NEBIVOLOL-WGR	WG	MP	C14251	P14251	56	5	28

hydrochloride)	WGR	NP
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[310] Schedule 1, Part 1, entry for Nintedanib in the form Capsule 100 mg

(a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP

(b) omit from the column headed "Circumstances": C13378 C13380 C13381 C13401 C13412 substitute: C17277 C17320 C17329 C17372 C17393

[311] Schedule 1, Part 1, entry for Nintedanib in the form Capsule 150 mg

(a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP

(b) omit from the column headed "Circumstances": C13378 C13380 C13381 C13401 C13412 substitute: C17277 C17320 C17329 C17372 C17393

[312] Schedule 1, Part 1, entry for Nivolumab in the form Injection concentrate for I.V. infusion 40 mg in 4 mL

(a) omit from the column headed "Circumstances": C13433

(b) insert in numerical order in the column headed "Circumstances": C17360

[313] Schedule 1, Part 1, entry for Nivolumab in the form Injection concentrate for I.V. infusion 100 mg in 10 mL

(a) omit from the column headed "Circumstances": C13433

(b) insert in numerical order in the column headed "Circumstances": C17360

[314] Schedule 1, Part 1, entry for Ofloxacin [Authorised Prescriber: MP]

omit from the column headed "Authorised Prescriber": MP substitute: MP NP

[315] Schedule 1, Part 1, entries for Olanzapine in the form Tablet 5 mg

omit:

Olanzapine	Tablet 5 mg	Oral	Olanzapine APOTEX	GX	MP NP	C4246 C5869	28	5	28
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[316] Schedule 1, Part 1, entries for Olmesartan with amlodipine in the form Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate)

omit:

Olmesartan with amlodipine	Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate)	Oral	Olmesartan/Amlod ipine 40/5 APOTEX	TX	MP NP	C4373	P4373	30	5	30
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Olmesartan with amlodipine	Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate)	Oral	Olmesartan/Amlodipine 40/5 APOTEX	TX	MP NP	C14839	P14839	60	5		30	
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[317] Schedule 1, Part 1, entries for Ondansetron in the form Tablet (orally disintegrating) 4 mg

omit:

Ondansetron	Tablet (orally disintegrating) 4 mg	Oral	Ondansetron Mylan ODT	AF	MP NP	C5618	P5618	4	0	V5618	4	
Ondansetron	Tablet (orally disintegrating) 4 mg	Oral	Ondansetron Mylan ODT	AF	MP	C5743	P5743	4	0	V5743	4	C(100)
Ondansetron	Tablet (orally disintegrating) 4 mg	Oral	Ondansetron Mylan ODT	AF	MP NP	C15193	P15193	10	1		10	

[318] Schedule 1, Part 1, after entry for Oxaliplatin in the form Solution concentrate for I.V. infusion 100 mg in 20 mL

insert:

Oxaliplatin	Solution concentrate for I.V. infusion 100 mg in 20 mL	Injection	OXALIPLATIN BAXTER	BX	MP			See Note 3	See Note 3		1	D(100)
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[319] Schedule 1, Part 1, entries for Pantoprazole in the form Tablet (enteric coated) 20 mg (as sodium sesquihydrate)

omit:

Pantoprazole	Tablet (enteric coated) 20 mg (as sodium sesquihydrate)	Oral	NOUMED PANTOPRAZOLE	VO	MP NP	C5444 C5512 C5529	P5444 P5512 P5529	30	5		30	
Pantoprazole	Tablet (enteric coated) 20 mg (as sodium sesquihydrate)	Oral	NOUMED PANTOPRAZOLE	VO	MP NP	C15574 C15575 C15633	P15574 P15575 P15633	60	5		30	

[320] Schedule 1, Part 1, entry for Pembrolizumab

(a) *omit from the column headed "Circumstances":* C16264 C16280

(b) *insert in numerical order in the column headed "Circumstances":* C17357 C17361

[321] Schedule 1, Part 1, entries for Phenytoin in the form Capsule containing phenytoin sodium 30 mg

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- omit from the column headed “Responsible Person” (all instances): UJ substitute (all instances): GO
- [322] Schedule 1, Part 1, entries for Phenytoin in the form Capsule containing phenytoin sodium 100 mg**
omit from the column headed “Responsible Person” (all instances): UJ substitute (all instances): GO
- [323] Schedule 1, Part 1, entries for Phenytoin in the form Oral suspension 30 mg per 5 mL, 500 mL**
omit from the column headed “Responsible Person” (all instances): UJ substitute (all instances): GO
- [324] Schedule 1, Part 1, entries for Phenytoin in the form Tablet 50 mg**
omit from the column headed “Responsible Person” (all instances): UJ substitute (all instances): GO
- [325] Schedule 1, Part 1, entry for Phytomenadione**
omit from the column headed “Section 100/ Prescriber Bag only”: D(MP) substitute: D(MP) D(NP)
- [326] Schedule 1, Part 1, entry for Pilocarpine in the form Eye drops containing pilocarpine hydrochloride 10 mg per mL, 15 mL [Maximum Quantity: 1; Number of Repeats: 5]**
omit from the column headed “Authorised Prescriber”: MP AO substitute: AO MP NP
- [327] Schedule 1, Part 1, entry for Pilocarpine in the form Eye drops containing pilocarpine hydrochloride 10 mg per mL, 15 mL [Maximum Quantity: 2; Number of Repeats: 5]**
omit from the column headed “Authorised Prescriber”: MP AO substitute: AO MP NP
- [328] Schedule 1, Part 1, entry for Pilocarpine in the form Eye drops containing pilocarpine hydrochloride 20 mg per mL, 15 mL [Maximum Quantity: 1; Number of Repeats: 5]**
omit from the column headed “Authorised Prescriber”: MP AO substitute: AO MP NP
- [329] Schedule 1, Part 1, entry for Pilocarpine in the form Eye drops containing pilocarpine hydrochloride 20 mg per mL, 15 mL [Maximum Quantity: 2; Number of Repeats: 5]**
omit from the column headed “Authorised Prescriber”: MP AO substitute: AO MP NP
- [330] Schedule 1, Part 1, entry for Pilocarpine in the form Eye drops containing pilocarpine hydrochloride 40 mg per mL, 15 mL [Maximum Quantity: 1; Number of Repeats: 5]**
omit from the column headed “Authorised Prescriber”: MP AO substitute: AO MP NP
- [331] Schedule 1, Part 1, entry for Pilocarpine in the form Eye drops containing pilocarpine hydrochloride 40 mg per mL, 15 mL [Maximum**
-

Quantity: 2; Number of Repeats: 5]

omit from the column headed "Authorised Prescriber": MP AO

substitute: AO MP NP

[332] Schedule 1, Part 1, entry for Pimecrolimus

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

[333] Schedule 1, Part 1, entry for Pirfenidone in the form Tablet 801 mg [Brand: ARX-Pirfenidone]

(a) *omit from the column headed "Authorised Prescriber": MP*

substitute: MP NP

(b) *omit from the column headed "Circumstances": C13380*

substitute: C17356

[334] Schedule 1, Part 1, entry for Pirfenidone in the form Tablet 801 mg [Brand: Pirfenidet]

(a) *omit from the column headed "Authorised Prescriber": MP*

substitute: MP NP

(b) *omit from the column headed "Circumstances": C13380*

substitute: C17356

[335] Schedule 1, Part 1, entry for Pirfenidone in the form Tablet 801 mg [Brand: Pirfenidone Ameda]

(a) *omit from the column headed "Authorised Prescriber": MP*

substitute: MP NP

(b) *omit from the column headed "Circumstances": C13380*

substitute: C17356

[336] Schedule 1, Part 1, entry for Pirfenidone in the form Tablet 801 mg [Brand: Pirfenidone Dr.Reddy's]

(a) *omit from the column headed "Authorised Prescriber": MP*

substitute: MP NP

(b) *omit from the column headed "Circumstances": C13380*

substitute: C17356

[337] Schedule 1, Part 1, entry for Pirfenidone in the form Tablet 801 mg [Brand: Pirfenidone Sandoz]

(a) *omit from the column headed "Authorised Prescriber": MP*

substitute: MP NP

(b) *omit from the column headed "Circumstances": C13380*

substitute: C17356

[338] Schedule 1, Part 1, entry for Pirfenidone in the form Tablet 267 mg [Brand: ARX-Pirfenidone]

(a) *omit from the column headed "Authorised Prescriber": MP*

substitute: MP NP

(b) *omit from the column headed "Circumstances": C13378 C13380 C13381*

substitute: C17277 C17320 C17329

[339] Schedule 1, Part 1, entry for Pirfenidone in the form Tablet 267 mg [Brand: Pirfenidet]

(a) *omit from the column headed "Authorised Prescriber": MP*

substitute: MP NP

(b) *omit from the column headed "Circumstances": C13378 C13380 C13381*

substitute: C17277 C17320 C17329

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- [340] **Schedule 1, Part 1, entry for Pirfenidone in the form Tablet 267 mg [Brand: Pirfenidone Ameda]**
 (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
 (b) omit from the column headed "Circumstances": C13378 C13380 C13381 substitute: C17277 C17320 C17329
- [341] **Schedule 1, Part 1, entry for Pirfenidone in the form Tablet 267 mg [Brand: Pirfenidone Dr.Reddy's]**
 (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
 (b) omit from the column headed "Circumstances": C13378 C13380 C13381 substitute: C17277 C17320 C17329
- [342] **Schedule 1, Part 1, entry for Pirfenidone in the form Tablet 267 mg [Brand: Pirfenidone Sandoz]**
 (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
 (b) omit from the column headed "Circumstances": C13378 C13380 C13381 substitute: C17277 C17320 C17329
- [343] **Schedule 1, Part 1, entry for Pregabalin in the form Capsule 25 mg [Brand: Lyrica]**
 omit from the column headed "Responsible Person": UJ substitute: GO
- [344] **Schedule 1, Part 1, entry for Pregabalin in the form Capsule 75 mg [Brand: Lyrica]**
 omit from the column headed "Responsible Person": UJ substitute: GO
- [345] **Schedule 1, Part 1, entry for Pregabalin in the form Capsule 150 mg [Brand: Lyrica]**
 omit from the column headed "Responsible Person": UJ substitute: GO
- [346] **Schedule 1, Part 1, entry for Pregabalin in the form Capsule 300 mg [Brand: Lyrica]**
 omit from the column headed "Responsible Person": UJ substitute: GO
- [347] **Schedule 1, Part 1, entry for Ranibizumab in the form Solution for intravitreal injection 1.65 mg in 0.165 mL pre-filled syringe [Maximum Quantity: 1; Number of Repeats: 5]**
 (a) omit from the column headed "Circumstances": C13388 C13402 substitute: C17288 C17395
 (b) omit from the column headed "Purposes": P13388 P13402 substitute: P17288 P17395
- [348] **Schedule 1, Part 1, entry for Ranibizumab in the form Solution for intravitreal injection 2.3 mg in 0.23 mL [Maximum Quantity: 1; Number of Repeats: 5]**
 (a) omit from the column headed "Circumstances": C13388 C13402 substitute: C17288 C17395
 (b) omit from the column headed "Purposes": P13388 P13402 substitute: P17288 P17395
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[349] Schedule 1, Part 1, entry for Rifaximin

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

[350] Schedule 1, Part 1, entries for Risperidone in the form Tablet 1 mg

omit:

Risperidone	Tablet 1 mg	Oral	NOUMED RISPERIDONE	VO	MP NP	C6898 C10020 C10021 C16048	P6898 P10020 P10021 P16048	60	2	60
Risperidone	Tablet 1 mg	Oral	NOUMED RISPERIDONE	VO	MP NP	C4246 C5907	P4246 P5907	60	5	60

[351] Schedule 1, Part 1, entries for Risperidone in the form Tablet 2 mg

omit:

Risperidone	Tablet 2 mg	Oral	NOUMED RISPERIDONE	VO	MP NP	C6898 C16048	P6898 P16048	60	2	60
Risperidone	Tablet 2 mg	Oral	NOUMED RISPERIDONE	VO	MP NP	C4246 C5907	P4246 P5907	60	5	60

[352] Schedule 1, Part 1, entries for Risperidone in the form Tablet 3 mg

omit:

Risperidone	Tablet 3 mg	Oral	NOUMED RISPERIDONE	VO	MP NP	C4246 C5907		60	5	60
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[353] Schedule 1, Part 1, entries for Risperidone in the form Tablet 4 mg

omit:

Risperidone	Tablet 4 mg	Oral	NOUMED RISPERIDONE	VO	MP NP	C4246 C5907		60	5	60
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[354] Schedule 1, Part 1, after entry for Rivaroxaban in the form Tablet 10 mg [Brand: Rivaroxaban-Teva; Maximum Quantity: 60; Number of Repeats: 5]

insert:

Rivaroxaban	Tablet 10 mg	Oral	RIVAXIB	MQ	MP	C4382	P4382	15	0	15
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NP										
Rivaroxaban	Tablet 10 mg	Oral	RIVAXIB	MQ	MP NP	C4402	P4402	15	1	15

[355] Schedule 1, Part 1, entry for Rotigotine in the form Transdermal patch 4.5 mg [Maximum Quantity: 28; Number of Repeats: 5]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- (b) omit from the column headed "Circumstances": C4190 substitute: C17323
- (c) omit from the column headed "Purposes": P4190 substitute: P17323

[356] Schedule 1, Part 1, entry for Rotigotine in the form Transdermal patch 4.5 mg [Maximum Quantity: 56; Number of Repeats: 5]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- (b) omit from the column headed "Circumstances": C15675 substitute: C17278
- (c) omit from the column headed "Purposes": P15675 substitute: P17278

[357] Schedule 1, Part 1, entry for Rotigotine in the form Transdermal patch 9 mg [Maximum Quantity: 28; Number of Repeats: 5]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- (b) omit from the column headed "Circumstances": C4204 substitute: C17323
- (c) omit from the column headed "Purposes": P4204 substitute: P17323

[358] Schedule 1, Part 1, entry for Rotigotine in the form Transdermal patch 9 mg [Maximum Quantity: 56; Number of Repeats: 5]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- (b) omit from the column headed "Circumstances": C15649 substitute: C17278
- (c) omit from the column headed "Purposes": P15649 substitute: P17278

[359] Schedule 1, Part 1, entry for Rotigotine in the form Transdermal patch 13.5 mg [Maximum Quantity: 28; Number of Repeats: 5]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- (b) omit from the column headed "Circumstances": C4204 substitute: C17323
- (c) omit from the column headed "Purposes": P4204 substitute: P17323

[360] Schedule 1, Part 1, entry for Rotigotine in the form Transdermal patch 13.5 mg [Maximum Quantity: 56; Number of Repeats: 5]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP

(b) omit from the column headed "Circumstances": C15649 substitute: C17278

(c) omit from the column headed "Purposes": P15649 substitute: P17278

[361] Schedule 1, Part 1, entry for Rotigotine in the form Transdermal patch 18 mg [Maximum Quantity: 28; Number of Repeats: 5]

(a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP

(b) omit from the column headed "Circumstances": C4204 substitute: C17323

(c) omit from the column headed "Purposes": P4204 substitute: P17323

[362] Schedule 1, Part 1, entry for Rotigotine in the form Transdermal patch 18 mg [Maximum Quantity: 56; Number of Repeats: 5]

(a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP

(b) omit from the column headed "Circumstances": C15649 substitute: C17278

(c) omit from the column headed "Purposes": P15649 substitute: P17278

[363] Schedule 1, Part 1, entries for Sertraline in the form Tablet 50 mg (as hydrochloride) [Brand: Zoloft]

omit from the column headed "Responsible Person" (all instances): UJ substitute (all instances): GO

[364] Schedule 1, Part 1, entries for Sertraline in the form Tablet 100 mg (as hydrochloride) [Brand: Zoloft]

omit from the column headed "Responsible Person" (all instances): UJ substitute (all instances): GO

[365] Schedule 1, Part 1, entry for Sildenafil in the form Tablet 20 mg (as citrate) [Brand: Revatio]

omit from the column headed "Responsible Person": UJ substitute: GO

[366] Schedule 1, Part 1, entries for Somatropin

substitute:

Somatropin	Injection 0.4 mg (1.2 i.u.) with diluent in single use syringe (without preservative)	Injection	Genotropin MiniQuick	PF	MP	C17136 C17137 C17141 C17142 C17143 C17144 C17148 C17151 C17157 C17158 C17160 C17162 C17166 C17167 C17171 C17186 C17187 C17188 C17189 C17195 C17196 C17197	See Note 3	See Note 3	7	D(100)
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						C17200 C17202 C17203 C17206 C17207 C17210 C17219 C17220 C17222 C17226 C17227 C17231 C17232 C17242 C17250 C17252 C17255 C17256 C17258 C17259 C17261 C17263 C17292 C17293 C17295 C17296 C17298 C17305 C17306 C17311				
Somatropin	Injection 0.6 mg (1.8 i.u.) with diluent in single use syringe (without preservative)	Injection	Genotropin MiniQuick	PF	MP	C17136 C17137 C17141 C17142 C17143 C17144 C17148 C17151 C17157 C17158 C17160 C17162 C17166 C17167 C17171 C17186 C17187 C17188 C17189 C17195 C17196 C17197 C17200 C17202 C17203 C17206 C17207 C17210 C17219 C17220 C17222 C17226 C17227 C17231 C17232 C17242 C17250 C17252 C17255 C17256 C17258 C17259 C17261 C17263 C17292 C17293 C17295 C17296 C17298 C17305 C17306 C17311	See Note 3	See Note 3	7	D(100)
Somatropin	Injection 0.8 mg (2.4 i.u.) with diluent in single use	Injection	Genotropin MiniQuick	PF	MP	C17136 C17137 C17141 C17142	See Note 3	See Note 3	7	D(100)

	syringe (without preservative)					C17143 C17144 C17148 C17151 C17157 C17158 C17160 C17162 C17166 C17167 C17171 C17186 C17187 C17188 C17189 C17195 C17196 C17197 C17200 C17202 C17203 C17206 C17207 C17210 C17219 C17220 C17222 C17226 C17227 C17231 C17232 C17242 C17250 C17252 C17255 C17256 C17258 C17259 C17261 C17263 C17292 C17293 C17295 C17296 C17298 C17305 C17306 C17311				
Somatropin	Injection 1 mg (3 i.u.) with diluent in single use syringe (without preservative)	Injection	Genotropin MiniQuick	PF	MP	C17136 C17137 C17141 C17142 C17143 C17144 C17148 C17151 C17157 C17158 C17160 C17162 C17166 C17167 C17171 C17186 C17187 C17188 C17189 C17195 C17196 C17197 C17200 C17202 C17203 C17206 C17207 C17210 C17219 C17220 C17222 C17226 C17227 C17231 C17232 C17242 C17250 C17252 C17255 C17256	See Note 3	See Note 3	7	D(100)

						C17258 C17259 C17261 C17263 C17292 C17293 C17295 C17296 C17298 C17305 C17306 C17311				
Somatropin	Injection 1.2 mg (3.6 i.u.) with diluent in single use syringe (without preservative)	Injection	Genotropin MiniQuick	PF	MP	C17136 C17137 C17141 C17142 C17143 C17144 C17148 C17151 C17157 C17158 C17160 C17162 C17166 C17167 C17171 C17186 C17187 C17188 C17189 C17195 C17196 C17197 C17200 C17202 C17203 C17206 C17207 C17210 C17219 C17220 C17222 C17226 C17227 C17231 C17232 C17242 C17250 C17252 C17255 C17256 C17258 C17259 C17261 C17263 C17292 C17293 C17295 C17296 C17298 C17305 C17306 C17311	See Note 3	See Note 3	7	D(100)
Somatropin	Injection 1.4 mg (4.2 i.u.) with diluent in single use syringe (without preservative)	Injection	Genotropin MiniQuick	PF	MP	C17136 C17137 C17141 C17142 C17143 C17144 C17148 C17151 C17157 C17158 C17160 C17162 C17166 C17167 C17171 C17186 C17187 C17188 C17189 C17195 C17196 C17197	See Note 3	See Note 3	7	D(100)

						C17200 C17202 C17203 C17206 C17207 C17210 C17219 C17220 C17222 C17226 C17227 C17231 C17232 C17242 C17250 C17252 C17255 C17256 C17258 C17259 C17261 C17263 C17292 C17293 C17295 C17296 C17298 C17305 C17306 C17311				
Somatropin	Injection 1.6 mg (4.8 i.u.) with diluent in single use syringe (without preservative)	Injection	Genotropin MiniQuick	PF	MP	C17136 C17137 C17141 C17142 C17143 C17144 C17148 C17151 C17157 C17158 C17160 C17162 C17166 C17167 C17171 C17186 C17187 C17188 C17189 C17195 C17196 C17197 C17200 C17202 C17203 C17206 C17207 C17210 C17219 C17220 C17222 C17226 C17227 C17231 C17232 C17242 C17250 C17252 C17255 C17256 C17258 C17259 C17261 C17263 C17292 C17293 C17295 C17296 C17298 C17305 C17306 C17311	See Note 3	See Note 3	7	D(100)
Somatropin	Injection 1.8 mg (5.4 i.u.) with diluent in single use	Injection	Genotropin MiniQuick	PF	MP	C17136 C17137 C17141 C17142	See Note 3	See Note 3	7	D(100)

	syringe (without preservative)					C17143 C17144 C17148 C17151 C17157 C17158 C17160 C17162 C17166 C17167 C17171 C17186 C17187 C17188 C17189 C17195 C17196 C17197 C17200 C17202 C17203 C17206 C17207 C17210 C17219 C17220 C17222 C17226 C17227 C17231 C17232 C17242 C17250 C17252 C17255 C17256 C17258 C17259 C17261 C17263 C17292 C17293 C17295 C17296 C17298 C17305 C17306 C17311				
Somatropin	Injection 2 mg (6 i.u.) with diluent in single use syringe (without preservative)	Injection	Genotropin MiniQuick	PF	MP	C17136 C17137 C17141 C17142 C17143 C17144 C17148 C17151 C17157 C17158 C17160 C17162 C17166 C17167 C17171 C17186 C17187 C17188 C17189 C17195 C17196 C17197 C17200 C17202 C17203 C17206 C17207 C17210 C17219 C17220 C17222 C17226 C17227 C17231 C17232 C17242 C17250 C17252 C17255 C17256	See Note 3	See Note 3	7	D(100)

						C17258 C17259 C17261 C17263 C17292 C17293 C17295 C17296 C17298 C17305 C17306 C17311				
Somatropin	Powder for injection 5 mg (15 i.u.) with diluent in pre- filled pen (with preservative)	Injection	Genotropin GoQuick	PF	MP	C14366 C16226 C16242 C16243 C17136 C17137 C17141 C17142 C17143 C17144 C17148 C17151 C17157 C17158 C17160 C17162 C17166 C17167 C17171 C17186 C17187 C17188 C17189 C17195 C17196 C17197 C17200 C17202 C17203 C17206 C17207 C17210 C17219 C17220 C17222 C17226 C17227 C17231 C17232 C17242 C17250 C17252 C17255 C17256 C17258 C17259 C17261 C17263 C17292 C17293 C17295 C17296 C17298 C17305 C17306 C17311	See Note 3	See Note 3	1	D(100)
Somatropin	Powder for injection 12 mg (36 i.u.) with diluent in pre- filled pen (with preservative)	Injection	Genotropin GoQuick	PF	MP	C14366 C16226 C16242 C16243 C17136 C17137 C17141 C17142 C17143 C17144 C17148 C17151 C17157 C17158 C17160 C17162 C17166 C17167	See Note 3	See Note 3	1	D(100)

						C17171 C17186 C17187 C17188 C17189 C17195 C17196 C17197 C17200 C17202 C17203 C17206 C17207 C17210 C17219 C17220 C17222 C17226 C17227 C17231 C17232 C17242 C17250 C17252 C17255 C17256 C17258 C17259 C17261 C17263 C17292 C17293 C17295 C17296 C17298 C17305 C17306 C17311				
Somatropin	Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative)	Injection	Omnitrope Surepal 5	SZ	MP	C17137 C17149 C17154 C17155 C17162 C17168 C17175 C17176 C17179 C17180 C17182 C17186 C17190 C17195 C17197 C17212 C17213 C17214 C17229 C17230 C17231 C17237 C17238 C17241 C17253 C17255 C17262 C17265 C17294 C17300 C17301 C17304 C17307 C17308 C17309 C17310 C17332 C17333 C17340 C17365 C17366 C17369 C17380 C17388	See Note 3	See Note 3	1	D(100)
Somatropin	Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge	Injection	Scitropin A	SA	MP	C17137 C17149 C17154 C17155	See Note 3	See Note 3	1	D(100)

	(with preservative)					C17162 C17168 C17175 C17176 C17179 C17180 C17182 C17186 C17190 C17195 C17197 C17212 C17213 C17214 C17229 C17230 C17231 C17237 C17238 C17241 C17253 C17255 C17262 C17265 C17294 C17300 C17301 C17304 C17307 C17308 C17309 C17310 C17332 C17333 C17340 C17365 C17366 C17369 C17380 C17388				
Somatropin	Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative) in pre-filled pen	Injection	Norditropin FlexPro	NO	MP	C14366 C16226 C16242 C16243 C17136 C17137 C17141 C17142 C17143 C17144 C17148 C17151 C17158 C17160 C17162 C17166 C17167 C17186 C17187 C17188 C17189 C17195 C17196 C17197 C17200 C17202 C17203 C17206 C17207 C17210 C17220 C17226 C17227 C17231 C17232 C17242 C17248 C17250 C17252 C17255 C17256 C17259 C17261 C17263 C17292 C17293 C17295 C17296	See Note 3	See Note 3	1	D(100)

						C17298 C17305 C17306					
Somatropin	Solution for injection 6 mg (18 i.u.) in 1.03 mL cartridge (with preservative)	Injection	Saizen	SG	MP	C14366 C16226 C16242 C16243 C17136 C17137 C17141 C17142 C17143 C17144 C17148 C17149 C17151 C17158 C17160 C17162 C17166 C17167 C17182 C17186 C17187 C17188 C17189 C17190 C17195 C17197 C17200 C17202 C17203 C17206 C17207 C17210 C17220 C17226 C17227 C17231 C17241 C17242 C17250 C17252 C17255 C17256 C17259 C17261 C17263 C17292 C17293 C17298 C17305 C17306 C17309	See Note 3	See Note 3	1	D(100)	
Somatropin	Solution for injection 10 mg (30 i.u.) in 1.5 mL cartridge (with preservative)	Injection	Omnitrope Surepal 10	SZ	MP	C17137 C17149 C17154 C17155 C17162 C17168 C17175 C17176 C17179 C17180 C17182 C17186 C17190 C17195 C17197 C17212 C17213 C17214 C17229 C17230 C17231 C17237 C17238 C17241 C17253 C17255 C17262 C17265 C17294 C17300	See Note 3	See Note 3	1	D(100)	

						C17301 C17304 C17307 C17308 C17309 C17310 C17332 C17333 C17340 C17365 C17366 C17369 C17380 C17388				
Somatropin	Solution for injection 10 mg (30 i.u.) in 1.5 mL cartridge (with preservative)	Injection	SciTropin A	SA	MP	C17137 C17149 C17154 C17155 C17162 C17168 C17175 C17176 C17179 C17180 C17182 C17186 C17190 C17195 C17197 C17212 C17213 C17214 C17229 C17230 C17231 C17237 C17238 C17241 C17253 C17255 C17262 C17265 C17294 C17300 C17301 C17304 C17307 C17308 C17309 C17310 C17332 C17333 C17340 C17365 C17366 C17369 C17380 C17388	See Note 3	See Note 3	1	D(100)
Somatropin	Solution for injection 10 mg (30 i.u.) in 1.5 mL cartridge (with preservative) in pre-filled pen	Injection	Norditropin FlexPro	NO	MP	C17136 C17137 C17141 C17142 C17143 C17144 C17148 C17151 C17158 C17160 C17162 C17166 C17167 C17186 C17187 C17188 C17189 C17195 C17196 C17197 C17200 C17202 C17203 C17206 C17207 C17210 C17220 C17226	See Note 3	See Note 3	1	D(100)

						C17227 C17231 C17232 C17242 C17248 C17250 C17252 C17255 C17256 C17259 C17261 C17263 C17292 C17293 C17295 C17296 C17298 C17305 C17306				
Somatropin	Solution for injection 12 mg (36 i.u.) in 1.5 mL cartridge (with preservative)	Injection	Saizen	SG	MP	C14366 C16226 C16242 C16243 C17136 C17137 C17141 C17142 C17143 C17144 C17148 C17149 C17151 C17158 C17160 C17162 C17166 C17167 C17182 C17186 C17187 C17188 C17189 C17190 C17195 C17197 C17200 C17202 C17203 C17206 C17207 C17210 C17220 C17226 C17227 C17231 C17241 C17242 C17250 C17252 C17255 C17256 C17259 C17261 C17263 C17292 C17293 C17298 C17305 C17306 C17309	See Note 3	See Note 3	1	D(100)
Somatropin	Solution for injection 15 mg (45 i.u.) in 1.5 mL cartridge (with preservative)	Injection	Omnitrope Surepal 15	SZ	MP	C17137 C17149 C17154 C17155 C17162 C17168 C17175 C17176 C17179 C17180 C17182 C17186 C17190 C17195	See Note 3	See Note 3	1	D(100)

						C17197 C17212 C17213 C17214 C17229 C17230 C17231 C17237 C17238 C17241 C17253 C17255 C17262 C17265 C17294 C17300 C17301 C17304 C17307 C17308 C17309 C17310 C17332 C17333 C17340 C17365 C17366 C17369 C17380 C17388				
Somatropin	Solution for injection 15 mg (45 i.u.) in 1.5 mL cartridge (with preservative) in pre-filled pen	Injection	Norditropin FlexPro	NO	MP	C17136 C17137 C17141 C17142 C17143 C17144 C17148 C17151 C17158 C17160 C17162 C17166 C17167 C17186 C17187 C17188 C17189 C17195 C17196 C17197 C17200 C17202 C17203 C17206 C17207 C17210 C17220 C17226 C17227 C17231 C17232 C17242 C17248 C17250 C17252 C17255 C17256 C17259 C17261 C17263 C17292 C17293 C17295 C17296 C17298 C17305 C17306	See Note 3	See Note 3	1	D(100)
Somatropin	Solution for injection 20 mg (60 i.u.) in 2.5 mL cartridge (with preservative)	Injection	Saizen	SG	MP	C17136 C17137 C17141 C17142 C17143 C17144 C17148 C17149	See Note 3	See Note 3	1	D(100)

C17151 C17158
 C17160 C17162
 C17166 C17167
 C17182 C17186
 C17187 C17188
 C17189 C17190
 C17195 C17197
 C17200 C17202
 C17203 C17206
 C17207 C17210
 C17220 C17226
 C17227 C17231
 C17241 C17242
 C17250 C17252
 C17255 C17256
 C17259 C17261
 C17263 C17292
 C17293 C17298
 C17305 C17306
 C17309

- [367] **Schedule 1, Part 1, entry for Testosterone in the form I.M. injection containing testosterone undecanoate 1,000 mg in 4 mL [Brand: Gonadron]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [368] **Schedule 1, Part 1, entry for Testosterone in the form I.M. injection containing testosterone undecanoate 1,000 mg in 4 mL [Brand: Reandron 1000]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [369] **Schedule 1, Part 1, entry for Testosterone in the form I.M. injection containing testosterone undecanoate 1,000 mg in 4 mL [Brand: REJUNON 1000]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [370] **Schedule 1, Part 1, entry for Testosterone in the form I.M. injection containing testosterone undecanoate 1,000 mg in 4 mL [Brand: Testosterone ADVZ 1000]**
omit from the column headed "Authorised Prescriber": MP *substitute: MP NP*
- [371] **Schedule 1, Part 1, entry for Testosterone in the form Transdermal cream 50 mg per mL, 50 mL [Maximum Quantity: 1; Number of Repeats: 1]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [372] **Schedule 1, Part 1, entry for Testosterone in the form Transdermal cream 50 mg per mL, 50 mL [Maximum Quantity: 2; Number of Repeats: 1]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [373] **Schedule 1, Part 1, entry for Testosterone in the form Transdermal gel 50 mg in 5 g sachet, 30 [Maximum Quantity: 1; Number of Repeats: 5]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [374] **Schedule 1, Part 1, entry for Testosterone in the form Transdermal gel 50 mg in 5 g sachet, 30 [Maximum Quantity: 2; Number of Repeats: 5]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [375] **Schedule 1, Part 1, entry for Testosterone in the form Transdermal gel (pump pack) 12.5 mg per 1.25 g dose, 60 doses, 2 [Maximum Quantity: 1; Number of Repeats: 4]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [376] **Schedule 1, Part 1, entry for Testosterone in the form Transdermal gel (pump pack) 12.5 mg per 1.25 g dose, 60 doses, 2 [Maximum Quantity: 2; Number of Repeats: 4]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [377] **Schedule 1, Part 1, entry for Testosterone in the form Transdermal gel (pump pack) 23 mg per 1.15 g dose, 56 doses [Maximum Quantity: 1; Number of Repeats: 5]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [378] **Schedule 1, Part 1, entry for Testosterone in the form Transdermal gel (pump pack) 23 mg per 1.15 g dose, 56 doses [Maximum Quantity: 2; Number of Repeats: 5]**

omit from the column headed "Authorised Prescriber": MP

substitute: MP NP

- [379] **Schedule 1, Part 1, entries for Timolol**

substitute:

Timolol	Eye drops 5 mg (as maleate) per mL, 5 mL	Application to the	Timoptol	MF	AO MP	1	5	1
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Timolol	Eye drops 5 mg (as maleate) per mL, 5 mL	eye Application to the eye	Timoptol	MF	AO MP NP	P14238	2	5	1
Timolol	Eye drops (gellan gum solution) 5 mg (as maleate) per mL, 2.5 mL	eye Application to the eye	Timoptol XE	MF	AO MP NP		1	5	1
Timolol	Eye drops (gellan gum solution) 5 mg (as maleate) per mL, 2.5 mL	eye Application to the eye	Timoptol XE	MF	AO MP NP	P14238	2	5	1

[380] Schedule 1, Part 1, entry for Tobramycin in the form Capsule containing powder for oral inhalation 28 mg (for use in podhaler)
[Maximum Quantity: 224; Number of Repeats: 0]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- (b) omit from the column headed "Circumstances": C4456 substitute: C17397
- (c) omit from the column headed "Purposes": P4456 substitute: P17397

[381] Schedule 1, Part 1, entry for Tobramycin in the form Capsule containing powder for oral inhalation 28 mg (for use in podhaler)
[Maximum Quantity: 224; Number of Repeats: 2]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- (b) omit from the column headed "Circumstances": C4513 substitute: C17405
- (c) omit from the column headed "Purposes": P4513 substitute: P17405

[382] Schedule 1, Part 1, entry for Tobramycin in the form Capsule containing powder for oral inhalation 28 mg (for use in podhaler)
[Maximum Quantity: 448; Number of Repeats: 2]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP
- (b) omit from the column headed "Circumstances": C15036 substitute: C17328
- (c) omit from the column headed "Purposes": P15036 substitute: P17328

[383] Schedule 1, Part 1, entry for Tobramycin in the form Solution for inhalation 300 mg in 5 mL [Brand: Tob; Maximum Quantity: 56; Number of Repeats: 2]

- (a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP

(b) omit from the column headed "Circumstances": C5520 substitute: C17349

(c) omit from the column headed "Purposes": P5520 substitute: P17349

[384] Schedule 1, Part 1, entry for Tobramycin in the form Solution for inhalation 300 mg in 5 mL [Brand: Tob; Maximum Quantity: 112; Number of Repeats: 2]

(a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP

(b) omit from the column headed "Circumstances": C15040 substitute: C17403

(c) omit from the column headed "Purposes": P15040 substitute: P17403

[385] Schedule 1, Part 1, entry for Tobramycin in the form Solution for inhalation 300 mg in 5 mL [Brand: TOBRAMYCIN SUN; Maximum Quantity: 56; Number of Repeats: 2]

(a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP

(b) omit from the column headed "Circumstances": C5520 substitute: C17349

(c) omit from the column headed "Purposes": P5520 substitute: P17349

[386] Schedule 1, Part 1, entry for Tobramycin in the form Solution for inhalation 300 mg in 5 mL [Brand: TOBRAMYCIN SUN; Maximum Quantity: 112; Number of Repeats: 2]

(a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP

(b) omit from the column headed "Circumstances": C15040 substitute: C17403

(c) omit from the column headed "Purposes": P15040 substitute: P17403

[387] Schedule 1, Part 1, entry for Tobramycin in the form Solution for inhalation 300 mg in 5 mL [Brand: Tobramycin WKT; Maximum Quantity: 56; Number of Repeats: 2]

(a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP

(b) omit from the column headed "Circumstances": C5520 substitute: C17349

(c) omit from the column headed "Purposes": P5520 substitute: P17349

[388] Schedule 1, Part 1, entry for Tobramycin in the form Solution for inhalation 300 mg in 5 mL [Brand: Tobramycin WKT; Maximum Quantity: 112; Number of Repeats: 2]

(a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP

(b) omit from the column headed "Circumstances": C15040 substitute: C17403

(c) omit from the column headed "Purposes": P15040 substitute: P17403

[389] Schedule 1, Part 1, entry for Trametinib in the form Tablet 500 micrograms [Maximum Quantity: 90; Number of Repeats: 5]

(a) insert in numerical order in the column headed "Circumstances": C17286

(b) insert in numerical order in the column headed "Purposes": P17286

[390] Schedule 1, Part 1, entry for Trametinib in the form Tablet 2 mg [Maximum Quantity: 30; Number of Repeats: 5]

(a) insert in numerical order in the column headed "Circumstances": C17286

(b) insert in numerical order in the column headed "Purposes": P17286

[391] Schedule 1, Part 1, entry for Travoprost in the form Eye drops 40 micrograms per mL, 2.5 mL [Maximum Quantity: 1; Number of Repeats: 5]

omit from the column headed "Authorised Prescriber": MP AO substitute: AO MP NP

[392] Schedule 1, Part 1, entry for Travoprost in the form Eye drops 40 micrograms per mL, 2.5 mL [Maximum Quantity: 2; Number of Repeats: 5]

omit from the column headed "Authorised Prescriber": MP AO substitute: AO MP NP

[393] Schedule 1, Part 1, entry for Travoprost with timolol in the form Eye drops 40 micrograms travoprost with timolol 5 mg (as maleate) per mL, 2.5 mL [Authorised Prescriber: MP; Maximum Quantity: 1; Number of Repeats: 5]

omit from the column headed "Authorised Prescriber": MP substitute: MP NP

[394] Schedule 1, Part 1, entry for Travoprost with timolol in the form Eye drops 40 micrograms travoprost with timolol 5 mg (as maleate) per mL, 2.5 mL [Maximum Quantity: 2; Number of Repeats: 5]

omit from the column headed "Authorised Prescriber": MP AO substitute: AO MP NP

[395] Schedule 1, Part 1, entry for Trimethoprim with sulfamethoxazole in the form Tablet 160 mg-800 mg [Brand: Bactrim DS; Maximum Quantity: 30; Number of Repeats: 2]

(a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP

(b) insert in the column headed "Purposes": P6201

[396] Schedule 1, Part 1, entry for Trimethoprim with sulfamethoxazole in the form Tablet 160 mg-800 mg [Brand: Resprim Forte; Maximum Quantity: 30; Number of Repeats: 2]

(a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP

(b) insert in the column headed "Purposes": P6201

[397] Schedule 1, Part 1, entry for Trimethoprim with sulfamethoxazole in the form Tablet 160 mg-800 mg [Brand: Septrin Forte; Maximum Quantity: 30; Number of Repeats: 2]

(a) omit from the column headed "Authorised Prescriber": MP substitute: MP NP

(b) insert in the column headed "Purposes": P6201

[398] Schedule 1, Part 1, entry for Ustekinumab in the form Injection 90 mg in 1 mL single use pre-filled syringe [Brand: Steqeyma; Maximum Quantity: 1; Number of Repeats: 1]

(a) omit from the column headed "Circumstances": C16862

(b) omit from the column headed "Circumstances": C16887

(c) insert in numerical order in the column headed "Circumstances": C17080 C17093

(d) omit from the column headed "Purposes": P16862

(e) omit from the column headed "Purposes": P16887

(f) insert in numerical order in the column headed "Purposes": P17080 P17093

[399] Schedule 1, Part 1, entry for Vancomycin in the form Capsule 125 mg (125,000 I.U.) (as hydrochloride) [Brand: Vancocin; Maximum Quantity: 40; Number of Repeats: 0]

omit from the column headed "Authorised Prescriber": MP substitute: MP NP

[400] Schedule 1, Part 1, entry for Vancomycin in the form Capsule 125 mg (125,000 I.U.) (as hydrochloride) [Brand: Vancomycin BNM 125mg; Maximum Quantity: 40; Number of Repeats: 0]

omit from the column headed "Authorised Prescriber": MP substitute: MP NP

[401] Schedule 1, Part 1, entry for Vancomycin in the form Capsule 250 mg (250,000 I.U.) (as hydrochloride) [Brand: Vancocin; Maximum Quantity: 40; Number of Repeats: 0]

omit from the column headed "Authorised Prescriber": MP substitute: MP NP

[402] Schedule 1, Part 1, entry for Vancomycin in the form Capsule 250 mg (250,000 I.U.) (as hydrochloride) [Brand: Vancomycin BNM 250mg; Maximum Quantity: 40; Number of Repeats: 0]

omit from the column headed "Authorised Prescriber": MP substitute: MP NP

[403] Schedule 1, Part 1, after entry for Vancomycin in the form Capsule 250 mg (250,000 I.U.) (as hydrochloride) [Brand: Vancomycin BNM

250mg]

insert:

Vancomycin	Powder for injection 500 mg (500,000 I.U.) (as hydrochloride)	Injection	Vancomycin Juno	XT	MP	C5717	P5717	2	0	1
Vancomycin	Powder for injection 500 mg (500,000 I.U.) (as hydrochloride)	Injection	Vancomycin Juno	XT	PDP	C5801	P5801	2	0	1
Vancomycin	Powder for injection 500 mg (500,000 I.U.) (as hydrochloride)	Injection	Vancomycin Juno	XT	MP MW	C5769	P5769	5	0	1
Vancomycin	Powder for injection 500 mg (500,000 I.U.) (as hydrochloride)	Injection	Vancomycin Juno	XT	MP	C5716	P5716	5	0	1

[404] Schedule 1, Part 1, after entry for Vancomycin in the form Powder for injection 500 mg (500,000 I.U.) (as hydrochloride) [Brand: Vancomycin Viatrix; Authorised Prescriber: MP; Maximum Quantity: 5; Number of Repeats: 0]

insert:

Vancomycin	Powder for injection 1 g (1,000,000 I.U.) (as hydrochloride)	Injection	Vancomycin Juno	XT	MP	C5717	P5717	1	0	1
Vancomycin	Powder for injection 1 g (1,000,000 I.U.) (as hydrochloride)	Injection	Vancomycin Juno	XT	PDP	C5801	P5801	1	0	1
Vancomycin	Powder for injection 1 g (1,000,000 I.U.) (as hydrochloride)	Injection	Vancomycin Juno	XT	MP MW	C5769	P5769	3	0	1
Vancomycin	Powder for injection 1 g (1,000,000 I.U.) (as hydrochloride)	Injection	Vancomycin Juno	XT	MP	C5716	P5716	3	0	1

[405] Schedule 1, Part 1, entry for Venlafaxine in the form Capsule (modified release) 37.5 mg (as hydrochloride) [Brand: Efexor-XR]

omit from the column headed "Responsible Person": UJ substitute: GO

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- [406] **Schedule 1, Part 1, entries for Venlafaxine in the form Capsule (modified release) 75 mg (as hydrochloride) [Brand: Efexor-XR]**
omit from the column headed “Responsible Person” (all instances): UJ substitute (all instances): GO
- [407] **Schedule 1, Part 1, entries for Venlafaxine in the form Capsule (modified release) 150 mg (as hydrochloride) [Brand: Efexor-XR]**
omit from the column headed “Responsible Person” (all instances): UJ substitute (all instances): GO
- [408] **Schedule 1, Part 1, entry for Ziprasidone in the form Capsule 20 mg (as hydrochloride) [Brand: Zeldox]**
omit from the column headed “Responsible Person”: UJ substitute: GO
- [409] **Schedule 1, Part 1, entry for Ziprasidone in the form Capsule 40 mg (as hydrochloride) [Brand: Zeldox]**
omit from the column headed “Responsible Person”: UJ substitute: GO
- [410] **Schedule 1, Part 1, entry for Ziprasidone in the form Capsule 60 mg (as hydrochloride) [Brand: Zeldox]**
omit from the column headed “Responsible Person”: UJ substitute: GO
- [411] **Schedule 1, Part 1, entry for Ziprasidone in the form Capsule 80 mg (as hydrochloride) [Brand: Zeldox]**
omit from the column headed “Responsible Person”: UJ substitute: GO
- [412] **Schedule 1, Part 2, omit entry for Adefovir**
- [413] **Schedule 1, Part 2, entries for Glyceryl trinitrate**
omit:

Glyceryl trinitrate	Transdermal patch 36 mg	Transdermal	Minitran 10	IL	30
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- [414] **Schedule 1, Part 2, omit entry for Ketoprofen**
- [415] **Schedule 1, Part 2, omit entry for Nevirapine**
- [416] **Schedule 1, Part 2, omit entry for Paracetamol**
- [417] **Schedule 1, Part 2, omit entry for Ramipril with felodipine**
- [418] **Schedule 4, Part 1, omit entry for Circumstances Code “C4190”**
- [419] **Schedule 4, Part 1, omit entry for Circumstances Code “C4204”**
- [420] **Schedule 4, Part 1, entry for Circumstances Code “C4343”**
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insert in alphabetical order in the column headed “Listed Drug”: Brinzolamide with brimonidine

- [421] **Schedule 4, Part 1, omit entry for Circumstances Code “C4456”**
- [422] **Schedule 4, Part 1, omit entry for Circumstances Code “C4513”**
- [423] **Schedule 4, Part 1, omit entry for Circumstances Code “C4572”**
- [424] **Schedule 4, Part 1, omit entry for Circumstances Code “C5224”**
- [425] **Schedule 4, Part 1, omit entry for Circumstances Code “C5461”**
- [426] **Schedule 4, Part 1, omit entry for Circumstances Code “C5520”**
- [427] **Schedule 4, Part 1, omit entry for Circumstances Code “C5630”**
- [428] **Schedule 4, Part 1, omit entry for Circumstances Code “C5727”**
- [429] **Schedule 4, Part 1, omit entry for Circumstances Code “C5789”**
- [430] **Schedule 4, Part 1, omit entry for Circumstances Code “C6169”**
- [431] **Schedule 4, Part 1, entry for Circumstances Code “C6188”**

omit from the column headed “Listed Drug”: Cefalexin

- [432] **Schedule 4, Part 1, omit entry for Circumstances Code “C8879”**
- [433] **Schedule 4, Part 1, omit entry for Circumstances Code “C10388”**
- [434] **Schedule 4, Part 1, omit entry for Circumstances Code “C12703”**
- [435] **Schedule 4, Part 1, omit entry for Circumstances Code “C12704”**
- [436] **Schedule 4, Part 1, omit entry for Circumstances Code “C12705”**
- [437] **Schedule 4, Part 1, omit entry for Circumstances Code “C12711”**
- [438] **Schedule 4, Part 1, omit entry for Circumstances Code “C12712”**
- [439] **Schedule 4, Part 1, omit entry for Circumstances Code “C12713”**
- [440] **Schedule 4, Part 1, omit entry for Circumstances Code “C12721”**

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- [441] Schedule 4, Part 1, omit entry for Circumstances Code “C12722”
- [442] Schedule 4, Part 1, omit entry for Circumstances Code “C12723”
- [443] Schedule 4, Part 1, omit entry for Circumstances Code “C12725”
- [444] Schedule 4, Part 1, omit entry for Circumstances Code “C12726”
- [445] Schedule 4, Part 1, omit entry for Circumstances Code “C12731”
- [446] Schedule 4, Part 1, omit entry for Circumstances Code “C12738”
- [447] Schedule 4, Part 1, omit entry for Circumstances Code “C12749”
- [448] Schedule 4, Part 1, omit entry for Circumstances Code “C12752”
- [449] Schedule 4, Part 1, omit entry for Circumstances Code “C12755”
- [450] Schedule 4, Part 1, omit entry for Circumstances Code “C12758”
- [451] Schedule 4, Part 1, omit entry for Circumstances Code “C12760”
- [452] Schedule 4, Part 1, omit entry for Circumstances Code “C12765”
- [453] Schedule 4, Part 1, omit entry for Circumstances Code “C12768”
- [454] Schedule 4, Part 1, omit entry for Circumstances Code “C12769”
- [455] Schedule 4, Part 1, omit entry for Circumstances Code “C12770”
- [456] Schedule 4, Part 1, omit entry for Circumstances Code “C12771”
- [457] Schedule 4, Part 1, omit entry for Circumstances Code “C12774”
- [458] Schedule 4, Part 1, omit entry for Circumstances Code “C12775”
- [459] Schedule 4, Part 1, omit entry for Circumstances Code “C12779”
- [460] Schedule 4, Part 1, omit entry for Circumstances Code “C12780”
- [461] Schedule 4, Part 1, omit entry for Circumstances Code “C12784”
- [462] Schedule 4, Part 1, omit entry for Circumstances Code “C12785”
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- [463] Schedule 4, Part 1, omit entry for Circumstances Code “C12789”
- [464] Schedule 4, Part 1, omit entry for Circumstances Code “C12790”
- [465] Schedule 4, Part 1, omit entry for Circumstances Code “C12791”
- [466] Schedule 4, Part 1, omit entry for Circumstances Code “C12793”
- [467] Schedule 4, Part 1, omit entry for Circumstances Code “C12798”
- [468] Schedule 4, Part 1, omit entry for Circumstances Code “C12803”
- [469] Schedule 4, Part 1, omit entry for Circumstances Code “C12805”
- [470] Schedule 4, Part 1, omit entry for Circumstances Code “C12806”
- [471] Schedule 4, Part 1, omit entry for Circumstances Code “C12809”
- [472] Schedule 4, Part 1, omit entry for Circumstances Code “C12810”
- [473] Schedule 4, Part 1, omit entry for Circumstances Code “C12812”
- [474] Schedule 4, Part 1, omit entry for Circumstances Code “C12817”
- [475] Schedule 4, Part 1, omit entry for Circumstances Code “C12820”
- [476] Schedule 4, Part 1, omit entry for Circumstances Code “C12821”
- [477] Schedule 4, Part 1, omit entry for Circumstances Code “C12824”
- [478] Schedule 4, Part 1, omit entry for Circumstances Code “C12826”
- [479] Schedule 4, Part 1, omit entry for Circumstances Code “C12829”
- [480] Schedule 4, Part 1, omit entry for Circumstances Code “C12831”
- [481] Schedule 4, Part 1, omit entry for Circumstances Code “C12832”
- [482] Schedule 4, Part 1, omit entry for Circumstances Code “C12834”
- [483] Schedule 4, Part 1, omit entry for Circumstances Code “C12855”
- [484] Schedule 4, Part 1, omit entry for Circumstances Code “C12857”
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- [485] Schedule 4, Part 1, omit entry for Circumstances Code “C12858”
- [486] Schedule 4, Part 1, omit entry for Circumstances Code “C12860”
- [487] Schedule 4, Part 1, omit entry for Circumstances Code “C12861”
- [488] Schedule 4, Part 1, omit entry for Circumstances Code “C12866”
- [489] Schedule 4, Part 1, omit entry for Circumstances Code “C12867”
- [490] Schedule 4, Part 1, omit entry for Circumstances Code “C12869”
- [491] Schedule 4, Part 1, omit entry for Circumstances Code “C12871”
- [492] Schedule 4, Part 1, omit entry for Circumstances Code “C12872”
- [493] Schedule 4, Part 1, omit entry for Circumstances Code “C12876”
- [494] Schedule 4, Part 1, omit entry for Circumstances Code “C12877”
- [495] Schedule 4, Part 1, omit entry for Circumstances Code “C12880”
- [496] Schedule 4, Part 1, omit entry for Circumstances Code “C12882”
- [497] Schedule 4, Part 1, omit entry for Circumstances Code “C12884”
- [498] Schedule 4, Part 1, omit entry for Circumstances Code “C12886”
- [499] Schedule 4, Part 1, omit entry for Circumstances Code “C12887”
- [500] Schedule 4, Part 1, omit entry for Circumstances Code “C12899”
- [501] Schedule 4, Part 1, omit entry for Circumstances Code “C12901”
- [502] Schedule 4, Part 1, omit entry for Circumstances Code “C12916”
- [503] Schedule 4, Part 1, omit entry for Circumstances Code “C12918”
- [504] Schedule 4, Part 1, omit entry for Circumstances Code “C12926”
- [505] Schedule 4, Part 1, omit entry for Circumstances Code “C12928”
- [506] Schedule 4, Part 1, omit entry for Circumstances Code “C12929”
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- [507] **Schedule 4, Part 1, entry for Circumstances Code “C13288”**
omit from the column headed “Listed Drug”: Somatropin
- [508] **Schedule 4, Part 1, entry for Circumstances Code “C13309”**
omit from the column headed “Listed Drug”: Somatropin
- [509] **Schedule 4, Part 1, omit entry for Circumstances Code “C13341”**
- [510] **Schedule 4, Part 1, omit entry for Circumstances Code “C13346”**
- [511] **Schedule 4, Part 1, omit entry for Circumstances Code “C13350”**
- [512] **Schedule 4, Part 1, omit entry for Circumstances Code “C13352”**
- [513] **Schedule 4, Part 1, omit entry for Circumstances Code “C13353”**
- [514] **Schedule 4, Part 1, omit entry for Circumstances Code “C13355”**
- [515] **Schedule 4, Part 1, omit entry for Circumstances Code “C13356”**
- [516] **Schedule 4, Part 1, omit entry for Circumstances Code “C13359”**
- [517] **Schedule 4, Part 1, omit entry for Circumstances Code “C13360”**
- [518] **Schedule 4, Part 1, omit entry for Circumstances Code “C13363”**
- [519] **Schedule 4, Part 1, omit entry for Circumstances Code “C13364”**
- [520] **Schedule 4, Part 1, omit entry for Circumstances Code “C13367”**
- [521] **Schedule 4, Part 1, omit entry for Circumstances Code “C13368”**
- [522] **Schedule 4, Part 1, omit entry for Circumstances Code “C13378”**
- [523] **Schedule 4, Part 1, omit entry for Circumstances Code “C13380”**
- [524] **Schedule 4, Part 1, omit entry for Circumstances Code “C13381”**
- [525] **Schedule 4, Part 1, omit entry for Circumstances Code “C13388”**
- [526] **Schedule 4, Part 1, omit entry for Circumstances Code “C13393”**
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- [527] Schedule 4, Part 1, omit entry for Circumstances Code “C13401”
- [528] Schedule 4, Part 1, entry for Circumstances Code “C13402”
omit from the column headed “Listed Drug”: Ranibizumab
- [529] Schedule 4, Part 1, omit entry for Circumstances Code “C13412”
- [530] Schedule 4, Part 1, omit entry for Circumstances Code “C13417”
- [531] Schedule 4, Part 1, omit entry for Circumstances Code “C13418”
- [532] Schedule 4, Part 1, omit entry for Circumstances Code “C13433”
- [533] Schedule 4, Part 1, omit entry for Circumstances Code “C13448”
- [534] Schedule 4, Part 1, omit entry for Circumstances Code “C14070”
- [535] Schedule 4, Part 1, entry for Circumstances Code “C14238”
(a) *insert in alphabetical order in the column headed “Listed Drug”*: Famotidine
(b) *insert in alphabetical order in the column headed “Listed Drug”*: Timolol
- [536] Schedule 4, Part 1, omit entry for Circumstances Code “C14610”
- [537] Schedule 4, Part 1, omit entry for Circumstances Code “C14619”
- [538] Schedule 4, Part 1, omit entry for Circumstances Code “C15036”
- [539] Schedule 4, Part 1, omit entry for Circumstances Code “C15040”
- [540] Schedule 4, Part 1, omit entry for Circumstances Code “C15094”
- [541] Schedule 4, Part 1, omit entry for Circumstances Code “C15326”
- [542] Schedule 4, Part 1, omit entry for Circumstances Code “C15406”
- [543] Schedule 4, Part 1, omit entry for Circumstances Code “C15432”
- [544] Schedule 4, Part 1, omit entry for Circumstances Code “C15649”
- [545] Schedule 4, Part 1, omit entry for Circumstances Code “C15675”
- [546] Schedule 4, Part 1, omit entry for Circumstances Code “C15919”
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- [547] Schedule 4, Part 1, omit entry for Circumstances Code “C15928”
- [548] Schedule 4, Part 1, omit entry for Circumstances Code “C16264”
- [549] Schedule 4, Part 1, omit entry for Circumstances Code “C16280”
- [550] Schedule 4, Part 1, omit entry for Circumstances Code “C16442”
- [551] Schedule 4, Part 1, omit entry for Circumstances Code “C16748”
- [552] Schedule 4, Part 1, omit entry for Circumstances Code “C16753”
- [553] Schedule 4, Part 1, omit entry for Circumstances Code “C16774”
- [554] Schedule 4, Part 1, after entry for Circumstances Code “C17114”

insert:

C17127	P17127	CN17127	Atezolizumab	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment 1 Patient must be undergoing combination treatment with bevacizumab and platinum-doublet chemotherapy. The condition must be non-squamous type non-small cell lung cancer (NSCLC). AND Patient must not have previously been treated for this condition in the metastatic setting. or The condition must have progressed after treatment with only one of: (i) tepotinib, (ii) seliperatinib, (iii) dabrafenib in combination with trametinib. AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer. AND Patient must have a WHO performance status of 0 or 1. AND The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation or an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material.	Compliance with Authority Required procedures - Streamlined Authority Code 17127
C17136	P17136	CN17136	Somatropin	Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth Recommendation of treatment 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	Compliance with Written Authority Required procedures

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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

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 2025 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. Details of the proposed prescription; 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 (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17137	P17137	CN17137	Somatropin	Short stature and slow growth Recommencement of treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature and slow growth. AND Patient must have had a lapse in 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	Compliance with Written Authority Required procedures

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 have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment). or

Patient must have had both: (i) a height no higher than the 1st percentile for age plus sex at the time of having commenced treatment with this drug, (ii) over the 12 month interval immediately prior to having commenced treatment, a growth velocity no greater than 8 cm/year where the patient had a bone/chronological age of no greater than 2.5 years. AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities 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.

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. AND

Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years

				or a bone age of at least 8 years. 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 2025 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. Details of the proposed prescription; 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 measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (where the patient's chronological age was higher than 2.5 years); OR (b) Confirmation that the patient has previously received treatment under the indication short stature associated with chronic renal insufficiency, has undergone a renal transplant and a 12 month period of observation following the transplant, and has 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; AND 4. Recent growth data (height and weight, not older than three months); AND 5. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND 6. The proprietary name (brand), form and strength of the growth hormone 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17141	P17141	CN17141	Somatropin	Short stature due to short stature homeobox (SHOX) gene disorders Recommencement of treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX)	Compliance with Written Authority Required procedures

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 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. 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 2025 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. Details of the proposed prescription; 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 (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17142	P17142	CN17142	Somatropin	Growth retardation secondary to an intracranial lesion, or cranial irradiation Recommencement of treatment 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	Compliance with Written Authority Required procedures

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

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 2025 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. Details of the proposed prescription; 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 (except for a patient whose
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				chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17143	P17143	CN17143	Somatropin	Short stature associated with Turner syndrome Recommencement of treatment 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 with Written Authority Required procedures

				compliance due to social/family problems. AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities 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. 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 2025 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. Details of the proposed prescription; 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 (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17144	P17144	CN17144	Somatropin	Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants Recommencement of treatment as a reclassified patient 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	Compliance with Written Authority Required procedures

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 a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes. AND

Patient must not have an active tumour or evidence of tumour growth or activity.

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 2025 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. Details of the proposed prescription; 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. 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17148	P17148	CN17148	Somatropin	Short stature associated with biochemical growth hormone deficiency Recommencement of treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with biochemical growth hormone deficiency. AND Patient must have had a lapse in 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	Compliance with Written Authority Required procedures

(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 have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment. or

Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment). or

Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment. or

Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment. AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

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. AND

Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

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 2025 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. Details of the proposed prescription; 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 measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing 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 (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17149	P17149	CN17149	Somatropin	Short stature associated with chronic renal insufficiency Recommencement of treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with chronic renal insufficiency. AND	Compliance with Written Authority Required procedures

Patient must have had a lapse in 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 1st percentile for age and sex immediately prior to commencing treatment. or

Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and a growth velocity less than or equal to the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment). or

Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment. or

Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5

years or less at commencement of 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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

Patient must be aged 3 years or older.

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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

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 2025 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. Details of the proposed prescription; 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 measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment
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				(except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17151	P17151	CN17151	Somatropin	Short stature associated with Turner syndrome Recommencement of treatment as a reclassified patient 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. 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	Compliance with Written Authority Required procedures

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 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 a condition with a known risk of malignancy including chromosomal abnormalities 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 height greater than or equal to 155.0 cm. AND

Patient must not have a bone age of 13.5 years or greater.

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 2025 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. Details of the proposed prescription; AND
 2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
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				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 (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17154	P17154	CN17154	Somatropin	Short stature due to short stature homeobox (SHOX) gene disorders Recommencement of treatment 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	Compliance with Written Authority Required procedures

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 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.

Patient must be aged 3 years or older.

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 2025 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. Details of the proposed prescription; AND
 2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
 3. Recent growth data (height and weight, not older than three months); AND
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				4. A bone age result performed within the last 12 months; AND 5. 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17155	P17155	CN17155	Somatropin	Short stature associated with biochemical growth hormone deficiency Recommencement of treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with biochemical growth hormone deficiency. AND Patient must have had a lapse in 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 with Written Authority Required procedures

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 have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment. or

Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment). or

Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment. or

Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment. AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

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. AND

Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

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 2025 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. Details of the proposed prescription; 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 measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at

				commencement of treatment); OR (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17157	P17157	CN17157	Somatropin	Short stature and poor body composition due to Prader-Willi syndrome Recommencement of treatment 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 Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the 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 had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most	Compliance with Written Authority Required procedures

recent treatment period (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 had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (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 had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (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 had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems. or

Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application 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 had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application 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 had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application 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 had a bone age at or above skeletal maturity (15.5 years for males

and 13.5 years for females) at the last application 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 had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application 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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

Patient must not have a chronological age of equal to or greater than 18 years.

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 2025 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. Details of the proposed prescription; 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: In patients whose chronological age is greater than 2.5 years, 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17158	P17158	CN17158	Somatropin	Short stature due to short stature homeobox (SHOX) gene disorders Recommencement of treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature due to short stature homeobox (SHOX) gene disorders. AND Patient must have had a lapse in 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	Compliance with Written Authority Required procedures

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 have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment. AND

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment). or

Patient must have had an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment. or

Patient must have had an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment. 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.

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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

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 2025 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. Details of the proposed prescription; AND 2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND 3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of 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 (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17160	P17160	CN17160	Somatropin	Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth Recommencement of treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth.	Compliance with Written Authority Required procedures

AND

Patient must have had a lapse in 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 have had a growth velocity above the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment). or

Patient must have had an annual growth velocity of greater than 14 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment. or

Patient must have had an annual growth velocity of greater than 8 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment. AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities 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.

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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

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 2025 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. Details of the proposed prescription; AND
 2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
 3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of 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 (except for a patient whose chronological age is 2.5 years or less); 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
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				treatment (with up to 1 repeat allowed). Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17162	P17162	CN17162	Somatropin	Short stature and slow growth Recommencement of treatment 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 a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes. AND	Compliance with Written Authority Required procedures

				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. 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. AND Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. 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 2025 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. Details of the proposed prescription; 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 (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17166	P17166	CN17166	Somatropin	Biochemical growth hormone deficiency and precocious puberty Recommencement of treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone	Compliance with Written Authority Required procedures

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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

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 2025 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. Details of the proposed prescription; 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 (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17167	P17167	CN17167	Somatropin	Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants Recommencement of treatment 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	Compliance with Written Authority Required procedures

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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

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 2025 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. Details of the proposed prescription; 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 (except for a patient whose chronological age is 2.5 years or less); 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.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not

				due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17168	P17168	CN17168	Somatropin	Growth retardation secondary to an intracranial lesion, or cranial irradiation Recommencement of treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation. AND Patient must have had a lapse in 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 which is under appropriate observation and management. or Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management. AND Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation	Compliance with Written Authority Required procedures

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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment. or

Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment). or

Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment. or

Patient must have had both a height above the 1st percentile for age and sex

immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment. AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities 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.

Patient must be aged 3 years or older.

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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

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 2025 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. Details of the proposed prescription; 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 measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing 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 which is under
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				appropriate observation and management; OR (b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17171	P17171	CN17171	Somatropin	Short stature and poor body composition due to Prader-Willi syndrome Recommencement of treatment as a reclassified patient 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	Compliance with Written Authority Required procedures

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 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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

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 2025 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. Details of the proposed prescription; AND

				2. A completed Growth Hormone Authority Application Supporting Information Form for commencement 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 or within the last 12 months, 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 at which skeletal maturity was achieved (if applicable) [Note: In patients whose chronological age is greater than 2.5 years, a bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity]; 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17175	P17175	CN17175	Somatropin	Biochemical growth hormone deficiency and precocious puberty Recommendation of treatment 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 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	Compliance with Written Authority Required procedures

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

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.

Patient must be aged 3 years or older.

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 2025 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. Details of the proposed prescription; 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
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				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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17176	P17176	CN17176	Somatropin	Short stature associated with Turner syndrome Recommencement of treatment 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 a condition with a known risk of malignancy including	Compliance with Written Authority Required procedures

				chromosomal abnormalities 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. 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. Patient must be aged 3 years or older. 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 2025 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. Details of the proposed prescription; 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 (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17179	P17179	CN17179	Somatropin	Biochemical growth hormone deficiency and precocious puberty Recommencement of treatment as a reclassified patient 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	Compliance with Written Authority Required procedures

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

Patient must be aged 3 years or older.

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 2025 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. Details of the proposed prescription; AND

				2. A completed Growth Hormone Authority Application Supporting Information Form for commencement 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17180	P17180	CN17180	Somatropin	Short stature associated with Turner syndrome Recommencement of treatment as a reclassified patient 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	Compliance with Written Authority Required procedures

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m²/week or greater for the most recent treatment period (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 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 a condition with a known risk of malignancy including chromosomal abnormalities 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 height greater than or equal to 155.0 cm. AND

Patient must not have a bone age of 13.5 years or greater.

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.

Patient must be aged 3 years or older.

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 2025 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. Details of the proposed prescription; 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
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				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 (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17182	P17182	CN17182	Somatropin	Short stature associated with chronic renal insufficiency Recommencement of treatment 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	Compliance with Written Authority Required procedures

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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

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.

Patient must be aged 3 years or older.

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 2025 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. Details of the proposed prescription; 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
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				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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17186	P17186	CN17186	Somatropin	Short stature and slow growth Continuing treatment 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 a condition with a known risk of malignancy including	Compliance with Written Authority Required procedures

				chromosomal abnormalities 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. Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. 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 2025 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. Details of the proposed prescription; 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 (except for a patient whose chronological age is 2.5 years or less); AND 5. The final adult height (in cm) of the patient's mother and father (where available); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17187	P17187	CN17187	Somatropin	Short stature due to short stature homeobox (SHOX) gene disorders Continuing treatment Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX)	Compliance with Written Authority Required procedures

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 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 2025 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. Details of the proposed prescription; 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 (except for a patient whose chronological age is 2.5 years or less); AND 5. The final adult height (in cm) of the patient's mother and father (where available); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17188	P17188	CN17188	Somatropin	Growth retardation secondary to an intracranial lesion, or cranial irradiation Continuing treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) 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	Compliance with Written Authority Required procedures

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 which is under appropriate observation and management. or

Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management. AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 had a height at or below the 1st percentile for age and sex

immediately prior to commencing treatment. or

Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment). or

Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment. or

Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment. AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities 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.

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 2025 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. Details of the proposed prescription; 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 measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment

				(except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing 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 which is under appropriate observation and management; OR (b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; 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 (except for a patient whose chronological age is 2.5 years or less); 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. An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17189	P17189	CN17189	Somatropin	Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants Continuing treatment as a reclassified patient 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	Compliance with Written Authority Required procedures

dose of 7.5mg/m²/week or greater for the most recent treatment period (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 a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes. AND

Patient must not have an active tumour or evidence of tumour growth or activity.

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 2025 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. Details of the proposed prescription; 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17190	P17190	CN17190	Somatropin	Short stature associated with chronic renal insufficiency Continuing treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) 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 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	Compliance with Written Authority Required procedures

dose of 9.5mg/m²/week or greater for the most recent treatment period (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 1st percentile for age and sex immediately prior to commencing treatment. or

Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and a growth velocity less than or equal to the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment). or

Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment. or

Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of 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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

Patient must be aged 3 years or older.

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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 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 2025 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. Details of the proposed prescription; 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 measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing 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.

				In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17195	P17195	CN17195	Somatropin	Short stature and slow growth Continuing treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) 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 have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25th	Compliance with Written Authority Required procedures

percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment). or

Patient must have had both: (i) a height no higher than the 1st percentile for age plus sex at the time of having commenced treatment with this drug, (ii) over the 12 month interval immediately prior to having commenced treatment, a growth velocity no greater than 8 cm/year where the patient had a bone/chronological age of no greater than 2.5 years. AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities 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.

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. AND

Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 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 2025 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. Details of the proposed prescription; 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 measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment
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				(where the patient's chronological age was higher than 2.5 years); OR (b) Confirmation that the patient has previously received treatment under the indication short stature associated with chronic renal insufficiency, has undergone a renal transplant and a 12 month period of observation following the transplant, and has 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; AND 4. 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 5. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17196	P17196	CN17196	Somatropin	Short stature associated with chronic renal insufficiency Continuing treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) 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	Compliance with Written Authority Required procedures

(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 1st percentile for age and sex immediately prior to commencing treatment. or

Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and a growth velocity less than or equal to the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment). or

Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment. or

Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of 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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 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 2025 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. Details of the proposed prescription; 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 measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR

(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing 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 (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17197	P17197	CN17197	Somatropin	Short stature associated with biochemical growth hormone deficiency Change of drug Patient must be undergoing existing PBS-subsidised growth hormone treatment where the prescribed drug is changing within the same PBS indication - subsidy through this treatment phase must not: (i) initiate treatment, (ii) recommence treatment, (iii) reclassify the PBS indication. Patient must have been treated with PBS-subsidised growth hormone for less than 32 weeks. or Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) having been demonstrated. or Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) not demonstrated due to at least one of: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance to treatment arising from social/family problems, (v) sub-optimal dosing (i.e. the dose was less than the permitted upper dose range). AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities 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. 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. AND Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. Definition:	Compliance with Written Authority Required procedures

				An adequate response to the preceding supply of growth hormone for which the patient is changing from is one where the patient, for their sex, has achieved at least one of: (a) the 50th percentile growth velocity for bone age; (b) an increase in height standard deviation score for chronological age; (c) a minimum growth velocity of 4 cm per year; (d) a mid-parental height standard deviation score. Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include: 1. 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. 2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years. Where growth data has been supplied within 3 months of this authority application, do not resupply this data. If the application is submitted through HPOS form upload or mail, it must include: (i) details of the proposed prescription; and (ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction. Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17200	P17200	CN17200	Somatropin	Biochemical growth hormone deficiency and precocious puberty Continuing treatment 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	Compliance with Written Authority Required procedures

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 a condition with a known risk of malignancy including chromosomal abnormalities 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 2025 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. Details of the proposed prescription; 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 (except for a patient whose chronological age is 2.5 years or less); AND
 5. The final adult height (in cm) of the patient's mother and father (where available);
AND
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				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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17202	P17202	CN17202	Somatropin	Short stature associated with biochemical growth hormone deficiency Continuing treatment 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 a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes. AND Patient must not have an active tumour or evidence of tumour growth or activity. AND	Compliance with Written Authority Required procedures

				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. Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. 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 2025 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. Details of the proposed prescription; 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 (except for a patient whose chronological age is 2.5 years or less); AND 5. The final adult height (in cm) of the patient's mother and father (where available); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17203	P17203	CN17203	Somatropin	Short stature associated with Turner syndrome Continuing treatment as a reclassified patient 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	Compliance with Written Authority Required procedures

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 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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

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 2025 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. Details of the proposed prescription; 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 (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17206	P17206	CN17206	Somatropin	Growth retardation secondary to an intracranial lesion, or cranial irradiation Continuing treatment 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	Compliance with Written Authority Required procedures

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 a condition with a known risk of malignancy including chromosomal abnormalities 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 2025 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. Details of the proposed prescription; 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 (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17207	P17207	CN17207	Somatropin	Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth Continuing treatment 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 a condition with a known risk of malignancy including chromosomal abnormalities 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	Compliance with Written Authority Required procedures

				must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2025 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. Details of the proposed prescription; 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 (except for a patient whose chronological age is 2.5 years or less); AND 5. The final adult height (in cm) of the patient's mother and father (where available); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17210	P17210	CN17210	Somatropin	Short stature associated with biochemical growth hormone deficiency Continuing treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) 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	Compliance with Written Authority Required procedures

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (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 have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment. or

Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment). or

Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment. or

Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment. AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3

micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

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. AND

Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 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 2025 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. Details of the proposed prescription; 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 measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing 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 (except for a patient whose chronological age is 2.5 years or less); 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.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

C17212	P17212	CN17212	Somatropin	Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants Continuing treatment 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 a condition with a known risk of malignancy including chromosomal abnormalities 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. 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 2025 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. Details of the proposed prescription; AND 2. A completed Growth Hormone Authority Application Supporting Information Form	Compliance with Written Authority Required procedures
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				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 final adult height (in cm) of the patient's mother and father (where available); 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. 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'. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17213	P17213	CN17213	Somatropin	Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth Continuing treatment 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).	Compliance with Written Authority Required procedures

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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

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 2025 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. Details of the proposed prescription; 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 final adult height (in cm) of the patient's mother and father (where available); 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.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening

				occurs for diabetes complications, particularly retinopathy.	
C17214	P17214	CN17214	Somatropin	Growth retardation secondary to an intracranial lesion, or cranial irradiation Continuing treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) 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 which is under appropriate observation and management. or Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management. AND Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3	Compliance with Written Authority Required procedures

micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment. or

Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment). or

Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment. or

Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement

of treatment. AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities 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.

Patient must be aged 3 years or older.

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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 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 2025 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. Details of the proposed prescription; 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 measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR

(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing 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 which is under appropriate observation and management; OR

(b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17219	P17219	CN17219	Somatropin	Short stature and poor body composition due to Prader-Willi syndrome Continuing treatment 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 have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and 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 had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and 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. or Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and 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).	Compliance with Written Authority Required procedures

or

Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and 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). or

Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and 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). or

Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and 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). or

Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and 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). or

Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and 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). or

Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and 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). or

Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and 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. or

Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and 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 or greater for the 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 had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and 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

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities 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.

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 2025 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. Details of the proposed prescription; 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: In patients whose chronological age is greater than 2.5 years, 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
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				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). In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17220	P17220	CN17220	Somatropin	Short stature due to short stature homeobox (SHOX) gene disorders Continuing treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) 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	Compliance with Written Authority Required procedures

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 have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment. AND

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment). or

Patient must have had an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment. or

Patient must have had an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment. 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.

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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 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 2025 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. Details of the proposed prescription; AND 2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND 3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of 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 (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17222	P17222	CN17222	Somatropin	Short stature and poor body composition due to Prader-Willi syndrome Continuing treatment as a reclassified patient 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	Compliance with Written Authority Required procedures

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 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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

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 2025 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. Details of the proposed prescription; 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 at which skeletal maturity was achieved (if applicable) [Note: In patients whose chronological age is greater than 2.5 years, a bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity]; 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17226	P17226	CN17226	Somatropin	Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants Continuing treatment 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	Compliance with Written Authority Required procedures

the 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 a condition with a known risk of malignancy including chromosomal abnormalities 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 2025 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. Details of the proposed prescription; 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 (except for a patient whose chronological age is 2.5 years or less); AND
 5. The final adult height (in cm) of the patient's mother and father (where available); AND
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				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. 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'. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17227	P17227	CN17227	Somatropin	Short stature associated with Turner syndrome Continuing treatment 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	Compliance with Written Authority Required procedures

				or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies). AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities 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 2025 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. Details of the proposed prescription; 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 (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17229	P17229	CN17229	Somatropin	Short stature associated with biochemical growth hormone deficiency Continuing treatment 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	Compliance with Written Authority Required procedures

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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

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 2025 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. Details of the proposed prescription; 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 final adult height (in cm) of the patient's mother and father (where available);
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				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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17230	P17230	CN17230	Somatropin	Short stature associated with Turner syndrome Continuing treatment 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 a condition with a known risk of malignancy including	Compliance with Written Authority Required procedures

				chromosomal abnormalities 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. 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 2025 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. Details of the proposed prescription; 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 (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17231	P17231	CN17231	Somatropin	Short stature and slow growth Change of drug Patient must be undergoing existing PBS-subsidised growth hormone treatment where the prescribed drug is changing within the same PBS indication - subsidy through this treatment phase must not: (i) initiate treatment, (ii) recommence treatment, (iii) reclassify the PBS indication. Patient must have been treated with PBS-subsidised growth hormone for less than 32 weeks. or Patient must have been treated with PBS-subsidised growth hormone for at least 32	Compliance with Written Authority Required procedures

weeks, with an adequate response to treatment (as defined further below) having been demonstrated. or

Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) not demonstrated due to at least one of: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance to treatment arising from social/family problems, (v) sub-optimal dosing (i.e. the dose was less than the permitted upper dose range). AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities 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.

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. AND

Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

Definition:

An adequate response to the preceding supply of growth hormone for which the patient is changing from is one where the patient, for their sex, has achieved at least one of:

- (a) the 50th percentile growth velocity for bone age;
- (b) an increase in height standard deviation score for chronological age;
- (c) a minimum growth velocity of 4 cm per year;
- (d) a mid-parental height standard deviation score.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

1. 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.
2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years.

Where growth data has been supplied within 3 months of this authority application, do

				not resupply this data. If the application is submitted through HPOS form upload or mail, it must include: (i) details of the proposed prescription; and (ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction. Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17232	P17232	CN17232	Somatropin	Short stature associated with chronic renal insufficiency Continuing treatment 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	Compliance with Written Authority Required procedures

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 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 2025 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. Details of the proposed prescription; 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 (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); 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.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

C17237	P17237	CN17237	Somatropin	Biochemical growth hormone deficiency and precocious puberty Continuing treatment as a reclassified patient 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 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin). or	Compliance with Written Authority Required procedures
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Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

Patient must be aged 3 years or older.

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 2025 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. Details of the proposed prescription; 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17238	P17238	CN17238	Somatropin	Short stature due to short stature homeobox (SHOX) gene disorders Continuing treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) 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	Compliance with Written Authority Required procedures

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 have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment. AND

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment). or

Patient must have had an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment. or

Patient must have had an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment. 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.
 Patient must be aged 3 years or older.
 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.
 An older child is defined as a male with a chronological age of at least 12 years or a
 bone age of at least 10 years, or a female with a chronological age of at least 10 years
 or a bone age of at least 8 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 2025 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. Details of the proposed prescription; AND
2. A completed Growth Hormone Authority Application Supporting Information Form
 for continuing treatment as a reclassified patient; AND
3. A minimum of 12 months of growth data (height and weight measurements) from
 immediately prior to commencement of treatment, or a minimum of 6 months of growth
 data from immediately prior to commencement of treatment if the patient was an older
 child at commencement of treatment; and the result of a bone age assessment
 performed within the 12 months immediately prior to commencement of treatment
 (except for a patient whose chronological age was 2.5 years or less at
 commencement of 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17241	P17241	CN17241	Somatropin	Short stature associated with chronic renal insufficiency Initial treatment 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. 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 have a current height at or below the 1st percentile for age and sex. or Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and a growth velocity less than or equal to the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child). or Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone age of 2.5 years or less. AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities 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.	Compliance with Written Authority Required procedures

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.

Patient must be aged 3 years or older.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

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 2025 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. Details of the proposed prescription; 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 measurements) or a minimum of 6 months of recent growth data for an older child.

The most recent data must not be more than three months old at the time of application; OR

(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; 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.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

C17242	P17242	CN17242	Somatropin	Short stature due to short stature homeobox (SHOX) gene disorders Initial treatment 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 have a current height at or below the 1st percentile for age and sex. AND Patient must have a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child). or Patient must have an annual growth velocity of 14 cm per year or less if the patient has a chronological age of 2 years or less. or Patient must have an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less. 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. 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. An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years. 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 2025 and request the appropriate number of vials/cartridges required to provide sufficient	Compliance with Written Authority Required procedures
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				drug for 16 weeks' worth of treatment (with up to 1 repeat allowed). The authority application must be in writing and must include: 1. Details of the proposed prescription; AND 2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND 3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; AND 4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17248	P17248	CN17248	Somatropin	Short stature associated with chronic renal insufficiency Initial treatment 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 have a current height at or below the 1st percentile for age and sex. or Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and a growth velocity less than or equal to the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an	Compliance with Written Authority Required procedures

older child). or

Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and an annual growth velocity of 14 cm per year or less if the patient has a chronological age of 2 years or less. or

Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less. AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities 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.

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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

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 2025 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. Details of the proposed prescription; 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 measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR
- (b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age

				and sex; AND 4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17250	P17250	CN17250	Somatropin	Biochemical growth hormone deficiency and precocious puberty Initial treatment 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep,	Compliance with Written Authority Required procedures

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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

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 2025 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. Details of the proposed prescription; AND
 2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
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				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 (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17252	P17252	CN17252	Somatropin	Short stature associated with biochemical growth hormone deficiency Initial treatment Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep,	Compliance with Written Authority Required procedures

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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 current height at or below the 1st percentile for age and sex. or

Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child). or

Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and an annual growth velocity of 14 cm per year or less if the patient has a chronological age of 2 years or less. or

Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less. AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities 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.

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. AND

Patient must be undergoing treatment for the stated indication with only one growth

				hormone at any given time. An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years. 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 2025 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. Details of the proposed prescription; 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 measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR (b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; AND 4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17253	P17253	CN17253	Somatropin	Short stature due to short stature homeobox (SHOX) gene disorders Initial treatment Patient must have diagnostic results consistent with a SHOX mutation/deletion,	Compliance with Written Authority Required procedures

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 have a current height at or below the 1st percentile for age and sex. AND

Patient must have a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child). or

Patient must have an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less. 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.

Patient must be aged 3 years or older.

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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

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 2025 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. Details of the proposed prescription; AND
2. A completed Growth Hormone Authority Application Supporting Information Form

				for initial treatment; AND 3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17255	P17255	CN17255	Somatropin	Short stature and slow growth Initial treatment Patient must have a current height at or below the 1st percentile for age and sex. AND Patient must have a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child). or Patient must have an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less. AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities 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. 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	Compliance with Written Authority Required procedures

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.

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. AND

Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

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 2025 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. Details of the proposed prescription; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); 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.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening

				occurs for diabetes complications, particularly retinopathy.	
C17256	P17256	CN17256	Somatropin	Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants Initial treatment 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. 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 a condition with a known risk of malignancy including chromosomal abnormalities 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. 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 2025 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. Details of the proposed prescription; 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not	Compliance with Written Authority Required procedures

				due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17258	P17258	CN17258	Somatropin	Short stature associated with chronic renal insufficiency Initial treatment 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 have a current height at or below the 1st percentile for age and sex. or Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and a growth velocity less than or equal to the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child). or Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and an annual growth velocity of 14 cm per year or less if the patient has a chronological age of 2 years or less. or Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less. AND Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities 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. 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. An older child is defined as a male with a chronological age of at least 12 years or a	Compliance with Written Authority Required procedures

				bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years. 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 2025 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. Details of the proposed prescription; 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 measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR (b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; AND 4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17259	P17259	CN17259	Somatropin	Growth retardation secondary to an intracranial lesion, or cranial irradiation Initial treatment Patient must have had an intracranial lesion which is under appropriate observation and management. or Patient must have received cranial irradiation without having had an intracranial	Compliance with Written Authority Required procedures

lesion, and is under appropriate observation and management. AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 current height at or below the 1st percentile for age and sex. or

Patient must have a current height above the 1st percentile for age and sex and a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child). or

Patient must have a current height above the 1st percentile for age and sex and an annual growth velocity of 14 cm per year or less if the patient has a chronological age of 2 years or less. or

Patient must have a current height above the 1st percentile for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone or

chronological age of 2.5 years or less. AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities 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.

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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

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 2025 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. Details of the proposed prescription; 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 measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR
- (b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); 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 which is under appropriate observation and management; OR
- (b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17261	P17261	CN17261	Somatropin	Short stature associated with Turner syndrome Initial treatment 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. 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 a condition with a known risk of malignancy including chromosomal abnormalities 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 height greater than or equal to 155.0cm. AND Patient must not have a bone age of 13.5 years or greater. 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 2025 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).	Compliance with Written Authority Required procedures

				The authority application must be in writing and must include: 1. Details of the proposed prescription; 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 (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17262	P17262	CN17262	Somatropin	Growth retardation secondary to an intracranial lesion, or cranial irradiation Initial treatment Patient must have had an intracranial lesion which is under appropriate observation and management. or Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management. AND Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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	Compliance with Written Authority Required procedures

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 current height at or below the 1st percentile for age and sex. or

Patient must have a current height above the 1st percentile for age and sex and a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child). or

Patient must have a current height above the 1st percentile for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone age of 2.5 years or less. AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities 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.

Patient must be aged 3 years or older.

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. An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years. 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 2025 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. Details of the proposed prescription; 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 measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR (b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; 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 which is under appropriate observation and management; OR (b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17263	P17263	CN17263	Somatropin	Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth	Compliance with Written Authority Required

	procedures
Initial treatment	
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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 have a growth velocity above the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child). or

Patient must have an annual growth velocity of greater than 14 cm per year if the patient has a chronological age of 2 years or less. or

Patient must have an annual growth velocity of greater than 8 cm per year if the patient has a bone or chronological age of 2.5 years or less. AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities 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.

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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

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 2025 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. Details of the proposed prescription; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17265	P17265	CN17265	Somatropin	Biochemical growth hormone deficiency and precocious puberty Initial treatment 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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	Compliance with Written Authority Required procedures

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

Patient must be aged 3 years or older.

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 2025 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. Details of the proposed prescription; 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17268	P17268	CN17268	Isotretinoin	Severe cystic acne The condition must be unresponsive to other therapy. Must be treated by a medical practitioner. or Must be treated by a nurse practitioner where this prescription is to continue existing therapy with this medicine.	Compliance with Authority Required procedures - Streamlined Authority Code 17268
C17270	P17270	CN17270	Clobetasol	Moderate to severe scalp psoriasis The condition must be inadequately controlled with either a vitamin D analogue or potent topical corticosteroid as monotherapy. or The condition must be inadequately controlled with combination use of a vitamin D	Compliance with Authority Required procedures - Streamlined Authority Code 17270

				analogue and potent topical corticosteroid. Patient must be at least 18 years of age.	
C17272	P17272	CN17272	Acitretin	Severe disorders of keratinisation Must be treated by a medical practitioner. or Must be treated by a nurse practitioner where this prescription is to continue existing therapy with this medicine.	Compliance with Authority Required procedures - Streamlined Authority Code 17272
C17277	P17277	CN17277	Nintedanib Pirfenidone	Idiopathic pulmonary fibrosis Initial treatment 2 - change or recommencement of treatment Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition. AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a prescriber who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) none of the aforementioned prescriber types, but has consulted one of these aforementioned prescriber types. AND Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis. AND Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.	Compliance with Authority Required procedures
C17278	P17278	CN17278	Rotigotine	Parkinson disease The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. AND The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination. Must be treated by a medical practitioner. or Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, (ii) the prescription continues existing therapy with this medicine.	
C17280	P17280	CN17280	Etanercept	Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a paediatric rheumatologist. or Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.	Compliance with Authority Required procedures

Patient must not have received PBS-subsidised treatment with a biological medicine for this condition. AND

Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate. or

Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months. AND

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

Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

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

(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:

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

(ii) shoulder, cervical spine 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 assessment of response to prior treatment must be documented in the patient's medical records.

				The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records: (a) the date of assessment of severe active juvenile idiopathic arthritis; and (b) details of prior treatment including dose and duration of treatment. At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
C17286	P17286	CN17286	Dabrafenib Trametinib	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Patient must have/have had a WHO performance status of no greater than 2 at treatment initiation with this drug for this condition. AND The condition must be positive for a BRAF V600E mutation. AND Patient must be receiving trametinib and dabrafenib concomitantly for this condition. Patient must be undergoing initial treatment with this drug. or Patient must be undergoing continuing treatment with this drug, with an absence of further disease progression while being treated with this drug. or Patient must be undergoing non-PBS-subsidised treatment with this drug for this PBS indication, with an absence of further disease progression since commencing non-PBS-subsidised supply.	Compliance with Authority Required procedures - Streamlined Authority Code 17286
C17288	P17288	CN17288	Ranibizumab	Proliferative diabetic retinopathy (PDR) and/or Diabetic macular oedema (DMO) Initial treatment Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment. This is only a	Compliance with Authority Required procedures

				requirement for patients being treated for DMO. AND The condition must be diagnosed by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. AND The condition must be diagnosed by optical coherence tomography. or The condition must be diagnosed by fluorescein angiography. or The condition must be diagnosed by retinal photography. AND The treatment must be the sole PBS-subsidised therapy for this condition. AND The treatment must be as monotherapy. or The treatment must be in combination with laser photocoagulation. AND Patient must not have previously received PBS-subsidised treatment with this drug for this indication for the same eye. Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. Authority approval for initial treatment of each eye must be sought. Details (date, unique identifying number/code or provider number) of one of the following diagnostic reports for each eye must be documented in the patient's medical records: (i) fluorescein angiogram report; (ii) optical coherence tomography report; (iii) retinal photography report.	
C17289	P17289	CN17289	Aflibercept Faricimab	Diabetic macular oedema (DMO) Initial treatment Patient must have visual impairment due to diabetic macular oedema. AND Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment. AND The condition must be diagnosed by optical coherence tomography. or The condition must be diagnosed by fluorescein angiography. AND The treatment must be as monotherapy. or The treatment must be in combination with laser photocoagulation. AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. Authority approval for initial treatment of each eye must be sought.	Compliance with Authority Required procedures

				Details (date, unique identifying number/code or provider number) of one of the following diagnostic reports for each eye must be documented in the patient's medical records: (i) fluorescein angiogram report; (ii) optical coherence tomography report.	
C17292	P17292	CN17292	Somatropin	Short stature associated with biochemical growth hormone deficiency Recommendation of treatment 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 recommendation 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 recommendation 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 recommendation 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 recommendation 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 recommendation 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 a condition with a known risk of malignancy including chromosomal abnormalities 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	Compliance with Written Authority Required procedures

				Patient must be female and must not have a bone age of 13.5 years or more. 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. AND Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. 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 2025 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. Details of the proposed prescription; 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 (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17293	P17293	CN17293	Somatropin	Biochemical growth hormone deficiency and precocious puberty Recommencement of treatment 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	Compliance with Written Authority Required procedures

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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

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 2025 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. Details of the proposed prescription; AND
 2. A completed Growth Hormone Authority Application Supporting Information Form
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				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 (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17294	P17294	CN17294	Somatropin	Short stature due to short stature homeobox (SHOX) gene disorders Recommencement of treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature due to short stature homeobox (SHOX) gene disorders. AND Patient must have had a lapse in 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	Compliance with Written Authority Required procedures

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m2/week or greater for the most recent treatment period (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 have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment. AND

Patient must have had a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment). or

Patient must have had an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment. or

Patient must have had an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment. 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.

Patient must be aged 3 years or older.

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.

An older child is defined as a male with a chronological age of at least 12 years or a

				bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years. 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 2025 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. Details of the proposed prescription; AND 2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND 3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17295	P17295	CN17295	Somatropin	Short stature associated with chronic renal insufficiency Recommencement of treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated	Compliance with Written Authority Required procedures

with chronic renal insufficiency. AND

Patient must have had a lapse in 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 1st percentile for age and sex immediately prior to commencing treatment. or

Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and a growth velocity less than or equal to the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment). or

Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment. or

Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual

growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of 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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

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 2025 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. Details of the proposed prescription; 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 measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment

				(except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing 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 (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17296	P17296	CN17296	Somatropin	Short stature associated with chronic renal insufficiency Recommencement of treatment 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	Compliance with Written Authority Required procedures

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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

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 2025 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. Details of the proposed prescription; 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 (except for a patient whose chronological age is 2.5 years or less); AND
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				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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17298	P17298	CN17298	Somatropin	Growth retardation secondary to an intracranial lesion, or cranial irradiation Recommencement of treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation. AND Patient must have had a lapse in 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	Compliance with Written Authority Required procedures

dose of 7.5mg/m2/week or greater for the most recent treatment period (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 which is under appropriate observation and management. or

Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management. AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment. or

Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment). or

Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment. or

Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment. AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities 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.

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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

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 2025 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. Details of the proposed prescription; AND
 2. A completed Growth Hormone Authority Application Supporting Information Form
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				for recommencement of treatment as a reclassified patient; AND 3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing 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 which is under appropriate observation and management; OR (b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; 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 (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17300	P17300	CN17300	Somatropin	Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth Recommencement of treatment 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	Compliance with Written Authority Required procedures

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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

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.

Patient must be aged 3 years or older.

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 2025 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. Details of the proposed prescription; AND
 2. A completed Growth Hormone Authority Application Supporting Information Form
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				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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17301	P17301	CN17301	Somatropin	Short stature associated with biochemical growth hormone deficiency Recommencement of treatment 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	Compliance with Written Authority Required procedures

				dose of 7.5mg/m2/week or greater for the most recent treatment period (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 a condition with a known risk of malignancy including chromosomal abnormalities 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. 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. AND Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. 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 2025 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. Details of the proposed prescription; 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17304	P17304	CN17304	Somatropin	Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth	Compliance with Written Authority Required

serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 have had a growth velocity above the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment). or

Patient must have had an annual growth velocity of greater than 14 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment. or

Patient must have had an annual growth velocity of greater than 8 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment. AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities 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.
Patient must be aged 3 years or older.

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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 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 2025 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. Details of the proposed prescription; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17305	P17305	CN17305	Somatropin	Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth Continuing treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) 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	Compliance with Written Authority Required procedures

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m2/week or greater for the most recent treatment period (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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 have had a growth velocity above the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment). or

Patient must have had an annual growth velocity of greater than 14 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment. or

Patient must have had an annual growth velocity of greater than 8 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment. AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities 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.

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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 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 2025 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. Details of the proposed prescription; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment

				performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of 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 (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17306	P17306	CN17306	Somatropin	Biochemical growth hormone deficiency and precocious puberty Continuing treatment as a reclassified patient 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	Compliance with Written Authority Required procedures

The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m²/week or greater for the most recent treatment period (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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

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 2025 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. Details of the proposed prescription; 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
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				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 (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17307	P17307	CN17307	Somatropin	Short stature due to short stature homeobox (SHOX) gene disorders Continuing treatment 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	Compliance with Written Authority Required procedures

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 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.

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 2025 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. Details of the proposed prescription; 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 final adult height (in cm) of the patient's mother and father (where available); 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.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

C17308	P17308	CN17308	Somatropin	Short stature associated with Turner syndrome Continuing treatment as a reclassified patient 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 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 a condition with a known risk of malignancy including	Compliance with Written Authority Required procedures
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				chromosomal abnormalities 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. Patient must be aged 3 years or older. 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 2025 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. Details of the proposed prescription; 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 (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17309	P17309	CN17309	Somatropin	Short stature associated with chronic renal insufficiency	Compliance with Written

	Continuing treatment 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 a condition with a known risk of malignancy including chromosomal abnormalities 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. 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	Authority Required procedures

				Arrangement 2025 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. Details of the proposed prescription; 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 final adult height (in cm) of the patient's mother and father (where available); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17310	P17310	CN17310	Somatropin	Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth Initial treatment 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. 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 10 mU/L or less than or equal to 3.3	Compliance with Written Authority Required procedures

micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 have a growth velocity above the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child). or

Patient must have an annual growth velocity of greater than 8 cm per year if the patient has a bone age of 2.5 years or less. AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities 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.
 Patient must be aged 3 years or older.
 An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.
 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 2025 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. Details of the proposed prescription; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17311	P17311	CN17311	Somatropin	Short stature and poor body composition due to Prader-Willi syndrome Initial treatment 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 a condition with a known risk of malignancy including chromosomal abnormalities 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. 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 2025 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. Details of the proposed prescription; AND	Compliance with Written Authority Required procedures

				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 at which skeletal maturity was achieved (if applicable) [Note: In patients whose chronological age is greater than 2.5 years, a bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity]; 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17313	P17313	CN17313	Evolocumab	Familial homozygous hypercholesterolaemia Initial treatment The treatment must be in conjunction with dietary therapy and exercise. AND The condition must have been confirmed by genetic testing. or The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 7. AND Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre. AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise. or Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin. or	Compliance with Authority Required procedures - Streamlined Authority Code 17313

				Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information. Must be treated by a specialist physician. or Must be treated by an authorised prescriber in consultation with a specialist physician. The qualifying LDL cholesterol level following at least 12 consecutive weeks of treatment with a statin (unless treatment with a statin is contraindicated or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be documented in the patient's medical records and must be no more than 8 weeks old. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. The following must be documented in the patient's medical records: (i) the qualifying Dutch Lipid Clinic Network Score; or (ii) the result of genetic testing confirming a diagnosis of familial homozygous hypercholesterolaemia One of the following must be documented in the patient's medical records regarding prior statin treatment: (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information. Patients with symptomatic atherosclerotic cardiovascular disease where LDL cholesterol cannot be measured due to hypertriglyceridaemia, may qualify under this authority application if they have a non-HDL in excess of 2.4 millimoles per litre.	
C17316	P17316	CN17316	Acitretin	Severe intractable psoriasis Must be treated by a medical practitioner. or Must be treated by a nurse practitioner where this prescription is to continue existing therapy with this medicine.	Compliance with Authority Required procedures - Streamlined Authority Code 17316

C17320	P17320	CN17320	Nintedanib Pirfenidone	Idiopathic pulmonary fibrosis Initial treatment 1 - new patient The condition must be diagnosed through a multidisciplinary team. AND Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months. AND Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height. AND Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7. AND Patient must not have had an acute respiratory infection at the time of FVC measurement. AND Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%. AND Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity. AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a prescriber who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) none of the aforementioned prescriber types, but has consulted one of these aforementioned prescriber types. AND Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis. AND Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis. AND Patient must be undergoing treatment with this pharmaceutical benefit only where the prescriber has explained to the patient/patient's guardian the following: (i) that certain diagnostic criteria must be met to be eligible to initiate treatment, (ii) continuing treatment is not based on quantified improvements in diagnostic measurements, but will be determined by clinician judgement. A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis. Document in the patient's medical records the qualifying FVC, FEV1/FVC ratio and DLCO measurements. Retain medical imaging in the patient's medical records. Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or	Compliance with Written Authority Required procedures
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				mail. If the application is submitted through HPOS form upload or mail, it must include: (a) details of the proposed prescription; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	
C17323	P17323	CN17323	Rotigotine	Parkinson disease The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination. Must be treated by a medical practitioner. or Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, (ii) the prescription continues existing therapy with this medicine.	
C17326	P17326	CN17326	Etanercept	Severe psoriatic arthritis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition. AND Patient must have demonstrated an adequate response to treatment with this drug. AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. 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	Compliance with Written Authority Required procedures

				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 used to determine response for all subsequent continuing treatments. The authority application must be made in writing and must include: (a) details of the proposed prescription(s); and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C17328	P17328	CN17328	Tobramycin	Proven <i>Pseudomonas aeruginosa</i> infection Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. AND Patient must have cystic fibrosis. AND Patient must have previously been issued with an authority prescription for tobramycin inhalation capsules. AND Patient must have demonstrated ability to tolerate the dry powder formulation following the initial 4-week treatment period, as agreed by the patient, the patient's family (in the case of paediatric patients) and the treating physician(s). Patient must be 6 years of age or older.	Compliance with Authority Required procedures - Streamlined Authority Code 17328

				Must be treated by a medical practitioner. or Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.	
C17329	P17329	CN17329	Nintedanib Pirfenidone	Idiopathic pulmonary fibrosis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition. AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a prescriber who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) none of the aforementioned prescriber types, but has consulted one of these aforementioned prescriber types. AND Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis. AND Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.	Compliance with Authority Required procedures
C17332	P17332	CN17332	Somatropin	Growth retardation secondary to an intracranial lesion, or cranial irradiation Recommencement of treatment 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	Compliance with Written Authority Required procedures

dose of 7.5mg/m²/week or greater for the most recent treatment period (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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

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.

Patient must be aged 3 years or older.

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 2025 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. Details of the proposed prescription; 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.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening

				occurs for diabetes complications, particularly retinopathy.	
C17333	P17333	CN17333	Somatropin	Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth Recommendation of treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) 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 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 recommendation 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 recommendation 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 recommendation 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 recommendation 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 recommendation 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	Compliance with Written Authority Required procedures

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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 have had a growth velocity above the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment). or

Patient must have had an annual growth velocity of greater than 14 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a

chronological age of 2 years or less at commencement of treatment. or

Patient must have had an annual growth velocity of greater than 8 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment. AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities 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.

Patient must be aged 3 years or older.

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.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

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 2025 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. Details of the proposed prescription; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17340	P17340	CN17340	Somatropin	Short stature associated with biochemical growth hormone deficiency Continuing treatment as a reclassified patient Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) 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	Compliance with Written Authority Required procedures

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 have had a height at or below the 1st percentile for age and sex immediately prior to commencing treatment. or

Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment). or

Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment. or

Patient must have had both a height above the 1st and at or below the 25th percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment. AND

Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

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. AND

Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 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 2025 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. Details of the proposed prescription; AND
 2. A completed Growth Hormone Authority Application Supporting Information Form
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				for continuing treatment as a reclassified patient; AND 3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17349	P17349	CN17349	Tobramycin	Proven Pseudomonas aeruginosa infection Patient must have cystic fibrosis. AND The treatment must be for management. Must be treated by a medical practitioner. or Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.	Compliance with Authority Required procedures - Streamlined Authority Code 17349

C17351	P17351	CN17351	Apremilast	Severe chronic plaque psoriasis Patient must not have achieved adequate response after at least 6 weeks of treatment with methotrexate prior to initiating treatment with this drug. or Patient must have a contraindication to methotrexate according to the Therapeutic Goods Administration (TGA) approved Product Information. or Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate. AND The condition must have caused significant interference with quality of life. AND Patient must not be undergoing concurrent PBS-subsidised treatment for psoriasis with each of: (i) a biological medicine, (ii) ciclosporin, (iii) deucravacitinib. Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician. or Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar. or Must be treated by a prescriber who is not any of the above, but where there is agreement to continue treatment (not initiate treatment) with one of the above practitioner types. Patient must be at least 18 years of age. For patients who do not demonstrate an adequate response to apremilast, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'. This assessment must be documented in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 17351
C17355	P17355	CN17355	Etanercept	Severe psoriatic arthritis Initial treatment - Initial 1 (new patient) Patient must not have received PBS-subsidised treatment with a biological medicine 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 16 weeks of treatment under this restriction. Patient must be at least 18 years of age.	Compliance with Written Authority Required procedures

Must be treated by a rheumatologist. or

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

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:

- (a) details of the proposed prescription(s); and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment

				failure.	
C17356	P17356	CN17356	Pirfenidone	Idiopathic pulmonary fibrosis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition. AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a prescriber who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) none of the aforementioned prescriber types, but has consulted one of these aforementioned prescriber types. AND Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis. AND Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.	Compliance with Authority Required procedures
C17357	P17357	CN17357	Pembrolizumab	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment - 6 weekly treatment regimen Patient must not have previously been treated for this condition in the metastatic setting. or The condition must have progressed after treatment with only one of: (i) tepotinib, (ii) seliperatinib, (iii) dabrafenib in combination with trametinib. AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer. AND Patient must have a WHO performance status of 0 or 1. AND The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material. AND The treatment must not exceed a total of 4 doses under this restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 17357
C17359	P17359	CN17359	Cemiplimab	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment - 3 weekly treatment regimen Patient must not have previously been treated for this condition in the metastatic setting. or The condition must have progressed after treatment with only one of: (i) tepotinib, (ii) seliperatinib, (iii) dabrafenib in combination with trametinib. AND	Compliance with Authority Required procedures - Streamlined Authority Code 17359

				Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer. AND Patient must have a WHO performance status of 0 or 1. AND The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material. AND The treatment must not exceed a total of 7 doses under this restriction.	
C17360	P17360	CN17360	Nivolumab	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial combination treatment (with ipilimumab) as first-line drug therapy The condition must be squamous type non-small cell lung cancer (NSCLC). AND Patient must not have previously been treated for this condition in the metastatic setting. or The condition must have progressed after treatment with only one of: (i) tepotinib, (ii) selipercatinib, (iii) dabrafenib in combination with trametinib. AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer. AND Patient must have a WHO performance status of 0 or 1. AND The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material. AND The treatment must be in combination with platinum-based chemotherapy for the first two cycles. AND The treatment must be in combination with ipilimumab.	Compliance with Authority Required procedures - Streamlined Authority Code 17360
C17361	P17361	CN17361	Pembrolizumab	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment - 3 weekly treatment regimen Patient must not have previously been treated for this condition in the metastatic setting. or The condition must have progressed after treatment with only one of: (i) tepotinib, (ii) selipercatinib, (iii) dabrafenib in combination with trametinib. AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer. AND Patient must have a WHO performance status of 0 or 1. AND The condition must not have evidence of an activating epidermal growth factor	Compliance with Authority Required procedures - Streamlined Authority Code 17361

				receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material. AND The treatment must not exceed a total of 7 doses under this restriction.	
C17365	P17365	CN17365	Somatropin	Growth retardation secondary to an intracranial lesion, or cranial irradiation Continuing treatment 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 a condition with a known risk of malignancy including chromosomal abnormalities 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. 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 2025 and request the appropriate number of vials/cartridges required to	Compliance with Written Authority Required procedures

				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. Details of the proposed prescription; 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 final adult height (in cm) of the patient's mother and father (where available); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17366	P17366	CN17366	Somatropin	Biochemical growth hormone deficiency and precocious puberty Continuing treatment 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	Compliance with Written Authority Required procedures

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 a condition with a known risk of malignancy including chromosomal abnormalities 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.

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 2025 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. Details of the proposed prescription; 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 final adult height (in cm) of the patient's mother and father (where available); 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.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

C17369	P17369	CN17369	Somatropin	Short stature associated with biochemical growth hormone deficiency Initial treatment Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 10 mU/L or less than or equal to 3.3 micrograms per litre 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 current height at or below the 1st percentile for age and sex. or Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child). or Patient must have a current height above the 1st and at or below the 25th percentiles for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone age of 2.5 years or less. AND Patient must not have a condition with a known risk of malignancy including	Compliance with Written Authority Required procedures
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chromosomal abnormalities 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.

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. AND

Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

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 2025 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. Details of the proposed prescription; 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 measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR
- (b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17372	P17372	CN17372	Nintedanib	Progressive fibrosing Interstitial lung disease Initial treatment The condition must be diagnosed through a multidisciplinary team. AND The condition must have chest imaging through high resolution computed tomography (HRCT) that is no older than 12 months, to support the diagnosis of the PBS indication. AND The condition must display, through HRCT, an affected area of no less than 10% (after rounding to the nearest multiple of 5). AND Patient must have a current (no older than 2 years) forced vital capacity (FVC) measurement of no less than 45% predicted, adjusted for each of: (i) age, (ii) gender, (iii) height. AND The condition must be of a progressive nature, observed by, in the 2 years leading up to this authority application, any of: (i) a worsening in relative FVC% predicted measurement of no less than 10%, (ii) a worsening in relative FVC% predicted measurement in the range 5-10%, combined with worsening of respiratory symptoms, (iii) a worsening in relative FVC% predicted measurement in the range 5-10%, combined with increases in fibrosis observed on HRCT; document at least one of (i) to (iii) in the patient's medical records. AND Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7. AND Patient must not have had an acute respiratory infection at the time of FVC measurement. AND Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin that is both: (i) at least 30% predicted, (ii) no greater than 80% predicted. AND The condition must not be interstitial lung disease due to idiopathic pulmonary fibrosis (apply under the correct PBS listing if it is). AND The condition must not be due to reversible causes (e.g. drug toxicity). Must be treated by a prescriber who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) none of the aforementioned prescriber types, but has consulted one of these aforementioned prescriber types. AND Patient must not be undergoing PBS-subsidised treatment simultaneously through the	Compliance with Written Authority Required procedures

				following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis. AND Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis. AND Patient must be undergoing treatment with this pharmaceutical benefit only where the prescriber has explained to the patient/patient's guardian the following: (i) that certain diagnostic criteria must be met to be eligible to initiate treatment, (ii) continuing treatment is not based on quantified improvements in diagnostic measurements, but will be determined by clinician judgement. Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) details of the proposed prescription; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). A multidisciplinary team is defined as comprising of at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis. Document in the patient's medical records the qualifying FVC, FEV1/FVC ratio and DLCO measurements. Retain medical imaging in the patient's medical records.	
C17374	P17374	CN17374	Etanercept	Severe chronic plaque psoriasis First continuing treatment, Face, hand, foot Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition. AND Patient must have demonstrated an adequate response to 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 under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. 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,	Compliance with Written Authority Required procedures

				as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The authority application must be made in writing and must include: (a) details of the proposed prescription(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes 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 first continuing or subsequent continuing treatment must be performed on the same affected area assessed at baseline. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C17378	P17378	CN17378	Lumasiran	Primary hyperoxaluria type 1 Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 October 2025. AND The condition must be primary hyperoxaluria type 1 confirmed by genetic testing. AND Patient must have undergone treatment with pyridoxine therapy prior to commencing non-PBS-subsidised treatment with this drug for this condition. or	Compliance with Written Authority Required procedures

				Patient must have a PH1 allele that is considered not responsive to pyridoxine therapy. or Patient must have been contraindicated for pyridoxine therapy as determined by the treating or consulting clinician prior to commencing non-PBS-subsidised treatment with this drug for this condition. AND Patient must have had urinary oxalate of at least 0.70 mmol/24 h/1.73 m² measured by mean 24-h urinary oxalate excretion from a valid 24-h urine collection prior to commencing treatment with this drug for this condition. or Patient must have urinary oxalate: creatinine ratio greater than the upper limit of normal based on age on at least two of three single-void collections during screening prior to commencing treatment with this drug for this condition. or Patient must have, prior to commencing treatment with this drug for this condition, clinical symptoms indicative of hyperoxaluria, such as (i) nephrocalcinosis; (ii) renal stones; (iii) renal impairment; (iv) systemic oxalosis. AND Patient must continue to demonstrate clinical benefit as assessed by the treating physician. AND Patient must not have previously undergone liver transplant for primary hyperoxaluria type 1. Must be treated by a nephrologist with experience in the management of hyperoxaluria. or Must be treated by a paediatrician with experience in the management of hyperoxaluria. or Must be treated by an authorised prescriber in consultation with one of the above specialty types. At the time of the authority application, prescribers should request the appropriate number of vials based on the patient's weight, as per the TGA approved Product Information. Up to 2 repeats may be requested. The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (i) details of the proposed prescription; and (ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	
C17380	P17380	CN17380	Somatropin	Short stature associated with Turner syndrome Initial treatment 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	Compliance with Written Authority Required procedures

consultation with a nominated specialist or consultant physician in paediatric endocrinology.

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 a condition with a known risk of malignancy including chromosomal abnormalities 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 height greater than or equal to 155.0 cm. AND

Patient must not have a bone age of 13.5 years or greater.

Patient must be aged 3 years or older.

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 2025 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. Details of the proposed prescription; 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 (except for a patient whose chronological age is 2.5 years or less); 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17381	P17381	CN17381	Cefalexin Flucloxacillin	Osteomyelitis Must be treated by a medical practitioner. or Must be treated by a nurse practitioner where this prescription is to continue existing therapy with this medicine.	Compliance with Authority Required procedures - Streamlined Authority Code 17381
C17387	P17387	CN17387	Dexamethasone	Diabetic macular oedema (DMO) Initial treatment Patient must have visual impairment due to diabetic macular oedema. AND Patient must have documented visual impairment defined as a best corrected visual acuity score between 78 and 39 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/32 to 20/160), in the eye proposed for treatment. AND The condition must be diagnosed by optical coherence tomography. or The condition must be diagnosed by fluorescein angiography. AND Patient must have had a cataract removed in the treated eye. or Patient must be scheduled for cataract surgery in the treated eye. AND Patient must have a contraindication to vascular endothelial growth factor (VEGF) inhibitors. or Patient must be unsuitable for treatment with VEGF inhibitors. or Patient must have failed prior treatment with VEGF inhibitors. AND The treatment must be as monotherapy. or The treatment must be in combination with laser photocoagulation. AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist. Authority approval for initial treatment of each eye must be sought. Details (date, unique identifying number/code or provider number) of one of the	Compliance with Authority Required procedures

				following diagnostic reports for each eye must be documented in the patient's medical records: (i) fluorescein angiogram report; (ii) optical coherence tomography report.	
C17388	P17388	CN17388	Somatropin	Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants Recommencement of treatment 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 a condition with a known risk of malignancy including chromosomal abnormalities 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. Must be treated by a medical practitioner in consultation with a nominated specialist or	Compliance with Written Authority Required procedures

				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. Patient must be aged 3 years or older. 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 2025 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. Details of the proposed prescription; 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. In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.	
C17391	P17391	CN17391	Deucravacitinib	Severe chronic plaque psoriasis Patient must not have achieved adequate response after at least 6 weeks of treatment with methotrexate prior to initiating treatment with this drug. or Patient must have a contraindication to methotrexate according to the Therapeutic Goods Administration (TGA) approved Product Information. or Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate. AND The condition must have caused significant interference with quality of life. AND Patient must not be undergoing concurrent PBS-subsidised treatment for psoriasis with each of: (i) a biological medicine, (ii) ciclosporin, (iii) apremilast. Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician. or Must be treated by a medical practitioner in consultation with one of the above	Compliance with Authority Required procedures - Streamlined Authority Code 17391

				specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar. or Must be treated by a prescriber who is not any of the above, but where there is agreement to continue treatment (not initiate treatment) with one of the above practitioner types. Patient must be at least 18 years of age. For patients who do not demonstrate an adequate response to deucravacitinib, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'. This assessment must be documented in the patient's medical records.	
C17393	P17393	CN17393	Nintedanib	Progressive fibrosing Interstitial lung disease Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition. Must be treated by a prescriber who is either: (i) a respiratory physician, (ii) a specialist physician, (iii) none of the aforementioned prescriber types, but has consulted one of these aforementioned prescriber types. AND Patient must not be undergoing PBS-subsidised treatment simultaneously through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis. AND Patient must not be undergoing sequential PBS-subsidised treatment through the following PBS indications: (i) progressive fibrosing interstitial lung disease, (ii) idiopathic pulmonary fibrosis.	Compliance with Authority Required procedures
C17395	P17395	CN17395	Ranibizumab	Proliferative diabetic retinopathy (PDR) and/or Diabetic macular oedema (DMO) Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye. AND The treatment must be the sole PBS-subsidised therapy for this condition. AND The treatment must be as monotherapy. or The treatment must be in combination with laser photocoagulation. Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.	Compliance with Authority Required procedures - Streamlined Authority Code 17395
C17397	P17397	CN17397	Tobramycin	Proven Pseudomonas aeruginosa infection	Compliance with Authority Required

				Initial treatment Patient must have cystic fibrosis. AND Patient must have been assessed for bronchial hyperresponsiveness as per the TGA-approved Product Information, with a negative test result. AND Patient must be participating in a four week trial of tobramycin inhalation powder and will be assessed for ability to tolerate the dry powder formulation in order to qualify for continued PBS-subsidised therapy. The trial commencement date must be documented in the patient's medical records. Patient must be 6 years of age or older. Must be treated by a medical practitioner. or Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.	procedures - Streamlined Authority Code 17397
C17398	P17398	CN17398	Capivasertib	Locally advanced or metastatic breast cancer The condition must be human epidermal growth factor receptor 2 (HER2) negative. AND The condition must be estrogen receptor positive. AND The treatment must be in combination with fulvestrant. AND The treatment must be following progression on at least one endocrine-based regimen in the metastatic setting. or The treatment must be following recurrence on or within 12 months of completing endocrine-based adjuvant therapy. A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug. Confirm that the following information is documented/retained in the patient's medical records once only with the first PBS prescription: 1) Evidence of HER2 gene amplification (evidence obtained in relation to past PBS treatment is acceptable). 2) Evidence of hormone receptor status.	Compliance with Authority Required procedures
C17399	P17399	CN17399	Lumasiran	Primary hyperoxaluria type 1 Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition. AND Patient must continue to demonstrate clinical benefit as assessed by the treating physician. AND Patient must not have previously undergone liver transplant for primary hyperoxaluria type 1.	Compliance with Written Authority Required procedures

				Must be treated by a nephrologist with experience in the management of hyperoxaluria. or Must be treated by a paediatrician with experience in the management of hyperoxaluria. or Must be treated by an authorised prescriber in consultation with one of the above specialty types. At the time of the authority application, prescribers should request the appropriate number of vials based on the patient's weight, as per the TGA approved Product Information. Up to 1 repeat may be requested for continuing treatment. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (i) details of the proposed prescription; and (ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	
C17401	P17401	CN17401	Lumasiran	Primary hyperoxaluria type 1 Initial treatment - loading dose The condition must be primary hyperoxaluria type 1 confirmed by genetic testing. AND Patient must have undergone treatment with pyridoxine therapy. or Patient must have a PH1 allele that is considered not responsive to pyridoxine therapy. or Patient must be contraindicated for pyridoxine therapy as determined by the treating or consulting clinician. AND Patient must have urinary oxalate greater than or equal to 0.70 mmol/24 h/1.73 m² measured by mean 24-h urinary oxalate excretion from a valid 24-h urine collection. or Patient must have urinary oxalate: creatinine ratio greater than the upper limit of normal based on age on at least two of three single-void collections during screening. or Patient must have clinical symptoms indicative of hyperoxaluria, such as (i) nephrocalcinosis; (ii) renal stones; (iii) renal impairment; (iv) systemic oxalosis. AND Patient must not have previously undergone liver transplant for primary hyperoxaluria type 1. Must be treated by a nephrologist with experience in the management of hyperoxaluria. or Must be treated by a paediatrician with experience in the management of hyperoxaluria. or	Compliance with Written Authority Required procedures

				Must be treated by an authorised prescriber in consultation with one of the above specialty types. At the time of the authority application, prescribers should request the appropriate number of vials based on the patient's weight, as per the TGA approved Product Information. Up to 2 repeats may be requested for initial treatment. The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (i) details of the proposed prescription; and (ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	
C17402	P17402	CN17402	Evolocumab	Familial homozygous hypercholesterolaemia Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition. AND The treatment must be in conjunction with dietary therapy and exercise. Must be treated by a medical practitioner. or Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.	Compliance with Authority Required procedures - Streamlined Authority Code 17402
C17403	P17403	CN17403	Tobramycin	Proven Pseudomonas aeruginosa infection The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. AND Patient must have cystic fibrosis. AND The treatment must be for management. Must be treated by a medical practitioner. or Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.	Compliance with Authority Required procedures - Streamlined Authority Code 17403
C17405	P17405	CN17405	Tobramycin	Proven Pseudomonas aeruginosa infection Continuing treatment Patient must have cystic fibrosis. AND Patient must have previously been issued with an authority prescription for tobramycin inhalation capsules. AND Patient must have demonstrated ability to tolerate the dry powder formulation following the initial 4-week treatment period, as agreed by the patient, the patient's family (in the	Compliance with Authority Required procedures - Streamlined Authority Code 17405

				case of paediatric patients) and the treating physician(s). Patient must be 6 years of age or older. Must be treated by a medical practitioner. or Must be treated by a nurse practitioner where patient care is being shared with a medical practitioner.	
C17406	P17406	CN17406	Budesonide	Eosinophilic oesophagitis Subsequent continuing treatment - Maintenance of remission Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction. AND Patient must have documented evidence of having achieved histologic remission while receiving Initial and First continuing PBS-subsidised treatment with this drug for this condition, defined as a peak eosinophil count of less than 5 eosinophils per high power field (hpf), corresponding to less than 16 eosinophils per mm2 hpf on oesophageal biopsy. AND The condition must not have progressed while being treated with this drug. Must be treated by a prescriber who is either: (i) gastroenterologist, (ii) surgeon experienced in the management of patients with eosinophilic oesophagitis, (iii) physician experienced in the management of patients with eosinophilic oesophagitis, (iv) a prescriber who is not any of the aforementioned prescriber types, but who has consulted at least one of the aforementioned prescriber types. Histologic assessment should be based on the peak eosinophils count derived, where necessary, from the evaluation of at least eight oesophageal biopsies (minimum of four collected from each of the mid and distal segments, with the distal segment biopsies taken at least 5 cm above the gastroesophageal junction). The histologic assessment should, where possible, be performed by, or in consultation with, the same physician or surgeon who confirmed the patient's diagnosis of eosinophilic oesophagitis. This assessment must be conducted within 48 weeks of initiating treatment to determine the patient's eligibility for continuing treatment. The histologic assessment should be conducted no later than 2 weeks prior to the patient completing the PBS-subsidised First continuing treatment course to avoid an interruption of supply for continuing therapy. Where a histologic assessment is not undertaken, the patient will not be eligible for ongoing treatment. The result of the histological assessment must be documented in the patient's medical records. First application for the subsequent continuing treatment of this condition must be received within 12 weeks of the histologic assessment.	Compliance with Authority Required procedures
C17409	P17409	CN17409	Budesonide	Eosinophilic oesophagitis First continuing treatment - until remission is confirmed	Compliance with Authority Required

	Patient must have previously received PBS-subsidised initial treatment with this drug for this condition. AND Patient must have demonstrated an adequate response to treatment with this drug for this condition. AND Patient must not receive more than 36 weeks of treatment under this restriction. Must be treated by a prescriber who is either: (i) gastroenterologist, (ii) surgeon experienced in the management of patients with eosinophilic oesophagitis, (iii) physician experienced in the management of patients with eosinophilic oesophagitis, (iv) a prescriber who is not any of the aforementioned prescriber types, but who has consulted at least one of the aforementioned prescriber types. Histologic assessment should be based on the peak eosinophils count derived, where necessary, from the evaluation of at least eight oesophageal biopsies (minimum of four collected from each of the mid and distal segments, with the distal segment biopsies taken at least 5 cm above the gastroesophageal junction). The histologic assessment should, where possible, be performed by, or in consultation with, the same physician or surgeon who confirmed the patient's diagnosis of eosinophilic oesophagitis. This assessment must be conducted within 48 weeks of initiating treatment to determine the patient's eligibility for continuing treatment. The histologic assessment should be conducted no later than 2 weeks prior to the patient completing the PBS-subsidised First continuing treatment course to avoid an interruption of supply for continuing therapy. Where a histologic assessment is not undertaken, the patient will not be eligible for ongoing treatment. The result of the histological assessment must be documented in the patient's medical records. First application for the subsequent continuing treatment of this condition must be received within 12 weeks of the histologic assessment.	procedures
[555]	Schedule 5, omit entry for Abacavir with lamivudine	
[556]	Schedule 5, entry for Abiraterone [GRP-29273] <i>insert as the first entry in the column headed "Brand": Abiraterone MedTas</i>	
[557]	Schedule 5, entry for Abiraterone [GRP-29283] <i>insert in the column headed "Brand" after entry for the brand "Abiraterone Dr.Reddy's": Abiraterone MedTas</i>	
[558]	Schedule 5, entry for Allopurinol [GRP-15579] <i>omit from the column headed "Brand": NOUMED ALLOPURINOL</i>	
[559]	Schedule 5, entry for Allopurinol [GRP-19808]	

insert in the column headed “Brand” after entry for the brand “NOUMED ALLOPURINOL”: Progout Viatris

[560] Schedule 5, entry for Amlodipine [GRP-19712]

omit from the column headed “Brand”: NOUMED AMLODIPINE

[561] Schedule 5, entry for Amlodipine [GRP-19809]

omit from the column headed “Brand”: NOUMED AMLODIPINE

[562] Schedule 5, entry for Amoxicillin [GRP-20061]

omit from the column headed “Brand”: NOUMED AMOXICILLIN

[563] Schedule 5, entry for Bisoprolol [GRP-19779]

omit from the column headed “Brand”: NOUMED BISOPROLOL

[564] Schedule 5, entry for Bisoprolol [GRP-19812]

omit from the column headed “Brand”: NOUMED BISOPROLOL

[565] Schedule 5, entry for Bisoprolol [GRP-19813]

omit from the column headed “Brand”: NOUMED BISOPROLOL

[566] Schedule 5, after entry for Bisoprolol [GRP-19813]

insert:

Bivalirudin	GRP-21165	Powder for I.V. injection 250 mg (as trifluoroacetate)	Injection	BIVALIRUDIN ARX BIVALIRUDIN MEDSURGE
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[567] Schedule 5, entry for Budesonide with formoterol [GRP-22141]

insert as the first entry in the column headed “Brand”: Bufomix EASYHALER 200/6

[568] Schedule 5, entry for Candesartan with hydrochlorothiazide [GRP-19559]

omit from the column headed “Brand”: NOUMED CANDESARTAN/HCT

[569] Schedule 5, entry for Candesartan with hydrochlorothiazide [GRP-19563]

omit from the column headed “Brand”: NOUMED CANDESARTAN/HCT

[570] Schedule 5, entry for Candesartan with hydrochlorothiazide [GRP-19567]

omit from the column headed “Brand”: NOUMED CANDESARTAN/HCT

[571] Schedule 5, entry for Cefalexin [GRP-20298]

substitute:

Cefalexin	GRP-20298	Capsule 500 mg (as monohydrate)	Oral	APO-Cephalexin Blooms The Chemist Cefalexin Cefalexin Sandoz Cephalex 500 Cephalexin generichealth CEPHALEXIN-WGR Ibilex 500 Keflex
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[572] Schedule 5, entry for Ciprofloxacin [GRP-19723]

substitute:

Ciprofloxacin	GRP-19723	Tablet 750 mg (as hydrochloride)	Oral	APO-Ciprofloxacin C-Flox 750 Ciprofloxacin Sandoz CIPROFLOXACIN-WGR Ciprol 750
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[573] Schedule 5, entry for Ciprofloxacin [GRP-19859]

substitute:

Ciprofloxacin	GRP-19859	Tablet 500 mg (as hydrochloride)	Oral	APO-Ciprofloxacin C-Flox 500 Ciprofloxacin Sandoz CIPROFLOXACIN-WGR Ciprol 500
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[574] Schedule 5, entry for Citalopram [GRP-19656]

omit from the column headed “Brand”: NOUMED CITALOPRAM

[575] Schedule 5, entry for Citalopram [GRP-19940]

omit from the column headed “Brand”: NOUMED CITALOPRAM

[576] Schedule 5, entry for Duloxetine [GRP-19918]

insert in the column headed “Brand” after entry for the brand “APO-Duloxetine”: Blooms The Chemist Duloxetine

[577] Schedule 5, entry for Duloxetine [GRP-19957]

insert in the column headed “Brand” after entry for the brand “APO-Duloxetine”: Blooms The Chemist Duloxetine

[578] Schedule 5, entries for Estradiol

omit:

Estradiol	GRP-28649	Transdermal patches 585 micrograms, 8	Transdermal	Estradiol Transdermal System (Sandoz, USA) Estradot 37.5
Estradiol	GRP-28652	Transdermal patches 1.56 mg, 8	Transdermal	Estradiol Transdermal System (Sandoz, USA) Estradot 100

[579] Schedule 5, entries for Etanercept

substitute:

Etanercept	GRP-26055	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Brenzys Enbrel Erelzi Nepexto
Etanercept	GRP-26055	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Brenzys Enbrel Erelzi

[580] Schedule 5, entry for Fluconazole [GRP-19858]

omit from the column headed “Brand”: Fluconazole APOTEX

[581] Schedule 5, after entry for Infliximab

insert:

Ipratropium	GRP-30136	Pressurised inhalation containing ipratropium bromide monohydrate 21 micrograms per dose, 200 doses (CFC-free formulation)	Inhalation by mouth	Atrovent Cipla Ipratropium
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[582] Schedule 5, entry for Irbesartan [GRP-19646]

omit from the column headed “Brand”: Noumed Irbesartan

[583] Schedule 5, entry for Irbesartan [GRP-19659]

omit from the column headed "Brand": Noumed Irbesartan

[584] Schedule 5, entry for Irbesartan [GRP-19742]

omit from the column headed "Brand": Noumed Irbesartan

[585] Schedule 5, entry for Lamivudine [GRP-19929]

omit from the column headed "Brand": Lamivudine Alphapharm

[586] Schedule 5, entry for Levetiracetam [GRP-19643]

substitute:

Levetiracetam	GRP-19643	Tablet 500 mg	Oral	APO-Levetiracetam Keppra Levactam Levetiracetam GH Levetiracetam Mylan Levetiracetam SZ Levetiracetam Viatris LEVETIRACETAM-WGR Levi 500 NOUMED LEVETIRACETAM
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[587] Schedule 5, entry for Mesalazine

substitute:

Mesalazine	GRP-27214	Tablet 1.2 g (prolonged release)	Oral	Mesalazine 1.2 TAKEDA MESALZ Mezavant MEZTAS
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[588] Schedule 5, entry for Metformin [GRP-19608]

insert in the column headed "Brand" after entry for the brand "METEX XR": Metformin Lupin XR

[589] Schedule 5, entry for Metformin [GRP-24200]

insert in the column headed "Brand" after entry for the brand "METEX XR": Metformin Lupin XR

[590] Schedule 5, entry for Montelukast [GRP-19556]

omit from the column headed "Brand": Montelukast APOTEX

[591] Schedule 5, entry for Montelukast [GRP-19572]

omit from the column headed "Brand": Montelukast APOTEX

[592] Schedule 5, entries for Morphine

omit:

Morphine	GRP-28109	Oral solution containing morphine hydrochloride trihydrate 2 mg per mL, 1 mL	Oral	Ordine 2
Morphine	GRP-28109	Oral solution containing morphine sulfate 10 mg per 5 mL in 100 mL bottle, 1 mL (S19A)	Oral	Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL
Morphine	GRP-28109	Oral solution containing morphine sulfate 10 mg per 5 mL in 300 mL bottle, 1 mL (S19A)	Oral	Morphine Oral Solution (Martindale Pharma) 10 mg/5 mL
Morphine	GRP-28497	Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 1 mL (S19A)	Oral	Morphini HCl Streuli

[593] Schedule 5, entry for Nebivolol [GRP-22506]

insert in the column headed "Brand" after entry for the brand "Nebivolol Sandoz": NEBIVOLOL-WGR

[594] Schedule 5, entry for Nebivolol [GRP-22511]

insert in the column headed "Brand" after entry for the brand "Nebivolol Sandoz": NEBIVOLOL-WGR

[595] Schedule 5, entry for Nebivolol [GRP-22512]

insert in the column headed "Brand" after entry for the brand "Nebivolol Sandoz": NEBIVOLOL-WGR

[596] Schedule 5, entry for Olanzapine [GRP-15921]

omit from the column headed "Brand": Olanzapine APOTEX

[597] Schedule 5, entry for Olmesartan with amlodipine [GRP-21160]

substitute:

Olmesartan with amlodipine	GRP-21160	Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate)	Oral	APO-OLMESARTAN/AMLODIPINE 40/5 OLMEKAR Olmesartan/Amlodipine - MYL 40/5 Olmesartan/Amlodipine Sandoz
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				OLMESARTAN AMLODIPINE-WGR 40/5 Pharmacor Olmesartan Amlodipine 40/5 Sevikar 40/5
[598]	Schedule 5, entry for Ondansetron in the form Tablet (orally disintegrating) 4 mg <i>omit from the column headed "Brand": Ondansetron Mylan ODT</i>			
[599]	Schedule 5, entry for Pantoprazole [GRP-19833] <i>substitute:</i>			
Pantoprazole	GRP-19833	Tablet (enteric coated) 20 mg (as sodium sesquihydrate)	Oral	APO-Pantoprazole APX-PANTOPRAZOLE BTC Pantoprazole Ozpan Panthron Pantoprazole APOTEX Pantoprazole generichealth Pantoprazole Sandoz PANTOPRAZOLE-WGR Salpraz Somac Sozol
[600]	Schedule 5, entry for Risperidone [GRP-19844] <i>omit from the column headed "Brand": NOUMED RISPERIDONE</i>			
[601]	Schedule 5, entry for Risperidone [GRP-19938] <i>omit from the column headed "Brand": NOUMED RISPERIDONE</i>			
[602]	Schedule 5, entry for Risperidone [GRP-20017] <i>omit from the column headed "Brand": NOUMED RISPERIDONE</i>			
[603]	Schedule 5, entry for Risperidone [GRP-20120] <i>omit from the column headed "Brand": NOUMED RISPERIDONE</i>			
[604]	Schedule 5, omit entries for Timolol			

[605] Schedule 5, after entry for Valsartan with hydrochlorothiazide [GRP-19966]

insert:

Vancomycin	GRP-19969	Powder for injection 500 mg (500,000 I.U.) (as hydrochloride)	Injection	Vancomycin Juno Vancomycin Viatris
Vancomycin	GRP-20043	Powder for injection 1 g (1,000,000 I.U.) (as hydrochloride)	Injection	Vancomycin Juno Vancomycin Viatris