ANZSPED
AUSTRALIA AND NEW ZEALAND SOCIETY FOR PAEDIATRIC ENDOCRINOLOGY AND DIABETES

Growth Hormone and IGF-1 PBS Eligibility and Prescribing Summary Guidelines 2025

Contents

1. Introduction

This document aims to summarise the important information for prescribers of growth promoting treatments in one place and serve as a quick reference guide. While efforts will be made to keep this document current, prescribers are advised that the unabridged source of information is in the documents and websites cited below from the Commonwealth Department of Health.

This document has been written by Prof Geoffrey Ambler (member and former chair of the Child and Adolescent Growth Committee of ANZSPED) with input from other committee members. Particular thanks to Dr Diane Jensen and Dr Myra Poon.

2. Definitions and terminology

1st adult height percentile	Male – 160.11cm Female - 148.02cm
1st height percentile for age and sex	For a person who is younger than 24 months, is determined with reference to the document titled *1st percentile length for age values – children ages 0-3 years*, published by the Department in 2011 and updated in 2014; and for a person who is older than 2 and younger than 21, is determined with reference to the document titled *1st percentile stature for age values – children ages 2-20 years*, published by the Department in 2011 and updated in 2014.
10th adult height percentile	Boys: 167.66cm Girls: 155.02cm
25th height percentile for age and sex	For a person who is younger than 24 months, is determined with reference to the document titled *25th percentile length for age values – children ages 0-3 years*, published by the Department in 2014; and for a person who is older than 2 and younger than 21, is determined with reference to the document titled *25th percentile stature for age values – children ages 2-20 years*, published by the Department in 2014.
Absolute dose	mg/wk.
Biochemical growth hormone deficiency (BGHD)	Peak serum growth hormone concentration ≤3.3 Ug/l in response to: 2 pharmacological tests (eg arginine, clonidine, glucagon, insulin) or 1 pharmacological test **AND** 1 physiological test (eg sleep, exercise) or 1 test (pharmacological or physiological) **WITH** other evidence of growth hormone deficiency such as structural CNS abnormalities known to be associated with growth hormone deficiency or low plasma IGF-1 ± IGFBP-3 levels
BMI	Body mass index.
BSA	Body surface area. BSA is calculated using the most recent height and weight measurements.
CDC 2000	The growth charts in the document titled *2000 CDC Growth Charts for the United States: Methods and Development,* published by the Centers for Disease Control and Prevention, US Department of Health and Human Services, dated May 2002, and available on the Department's website at http://www.cdc.gov/GROWTHcharts.
Chronic renal insufficiency	Estimated glomerular filtration rate (GFR) less than 30 ml/minute/1.73 m^2. Estimates of GFR are usually made using the Schwartz equation.
Dose	mg/m^2/wk.
DTPA	Diethylenetriamene penta-acetate.

GHAC	Growth Hormone Advisory Committee.
Growth Velocity (HV), or Height velocity (HV)	means the amount a person has grown over[1]: (a) 6 months, if the person is an older child; and 12 months (or another period if specified), if the person is not an older child.
Ideal body weight for height	Derived by calculating the 50th percentile weight for current height.
Maturational or constitutional delay	Refers to a situation in which: • the onset of puberty is delayed (beyond 12 years in girls or 14 years in boys); and • growth velocity is below the 25th percentile for bone age and sex; and • there is absence of any evidence of pathological conditions (identified through clinical tests such as growth hormone stimulation tests, TSH, FT4, Coeliac screening, Karyotype); and • bone age is delayed by 2 years or more.
MPH	Mid parental height.
Older child	Male: chronological age ≥ 12.0 years or bone age ≥ 10.0 years Female: chronological age ≥ 10.0 years or bone age ≥ 8.0 years
Percentile	• height percentile of a person in relation to age and sex (other than the 1st percentile for age and sex, the 25th percentile for age and sex, the 1st adult height percentile or the 10th adult height percentile) is determined with reference to CDC 2000; and • body mass index percentile of a person in relation to age and sex, is determined with reference to CDC 2000; and • growth velocity percentile of a person in relation to bone age and sex is determined using the charts of Tanner and Davies, *Journal of Paediatrics,* Volume 107, Issue 3 in September 1985.
PBAC	Pharmaceutical Benefits Advisory Committee.
PBS	Pharmaceutical Benefits Scheme.
Precocious puberty	Female: The onset of puberty before the chronological age of 8, demonstrated by Tanner stage 2 breast or pubic hair development or the onset of menarche before the age of 10. Male: The onset of puberty before the chronological age of 9, demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4mls.
SDS	Standard deviation score.
Short stature	Height below the 1st percentile for age, measured using the Centers for Disease Control and Prevention growth charts, available at www.cdc.gov/growthcharts/.
Skeletal maturity	Bone age ≥13.5 years (female) or ≥15.5 years (male). This skeletal maturity represents 97.5% of estimated final height.
Turner Syndrome – growth curve for girls	Means the Turner Syndrome height charts, Growth curve for girls with Turner Syndrome, in the document by Lyon AJ, Preece MA and Grant DB, 1985, *Archives of Disease in Childhood*, Volume 60, p 932-935.
Turner Syndrome – Ranke growth velocity chart	Means Figure 4: Mean height velocities in patients with Turner Syndrome observed by different investigators (Ranke series) in the document titled *Turner Syndrome: Spontaneous growth in 150 cases and review of literature* by Ranke et al, dated 1983 and published in *European Journal of Paediatrics*, volume 141, pages 81-88.
Uncontrolled morbid obesity	Body weight greater than 200% of ideal body weight for height based on CDC 2000 data.
Untreated PWS standards	Reference from Butler et al, 1991, Standards for Selected Anthropometric Measurements in Prader-Willi Syndrome, *Paediatrics,* vol 88, No 4, p853-860.

3. Administrative and regulatory aspects

PBS and Section 100 Special Arrangement

Growth Hormone (GH) is subsidised by the Australian Government through the Pharmaceutical Benefits Scheme (PBS). In addition to the drugs and medicinal preparations available under normal PBS arrangements, GH is available through special PBS arrangements made by the Minister under section 100 of the National Health Act 1953. The supply of GH under section 100 of the Act is provided for in the National Health (Growth Hormone Program) Special Arrangement 2015 and amendments. The Special Arrangement provides the legal basis for the provision of subsidised GH via the PBS. These Guidelines should be read in conjunction with the Special Arrangement, available at https://www.legislation.gov.au/F2015L01368/latest/text.

The Services Australia website describes in detail the processes for prescribing PBS subsidized growth treatments:
Paediatric growth hormone:
https://www.servicesaustralia.gov.au/growth-hormone-deficiency-paediatric-patients?context=20

Late onset GHD / adult GHD:
https://www.servicesaustralia.gov.au/growth-hormone-deficiency-childhood-onset-or-late-onset?context=20

Severe primary IGF-1 deficiency:
https://www.servicesaustralia.gov.au/severe-growth-failure-with-primary-insulin-growth-factor-1-deficiency?context=20

Prescribing Process Overview

Some key points:

- Applications are best based made via the online PBS authorities system via HPOS, which gives an instant result
- Applications can also be made via writing and HPOS Form upload, or writing and mail to PBS Complex Drugs Programs
- The patient must be treated by a specialist or consultant physician in paediatric endocrinology or a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology
- For growth hormone:
    - Doses and number of pens/cartridges are calculated using the calculators provided at the above websites.
    - The initial script gives 16 weeks of supply with 1 repeat for 16 weeks supply
    - Subsequent scripts are 13 weeks supply with 1 repeat for 13 weeks supply
    - Prescriptions are only valid for 6 months
    - Reapplications for ongoing treatment are made every 6 months (window 4-8 months)

4. Steps to initially prescribe growth promoting therapies as a PBS subsidized medication

Initial Prescription Steps

1. Determine patient eligibility according to diagnostic category and any exclusion criteria

   This requires reference to or a knowledge of the PBS eligibility criteria.

2. Decide on which product and dose you are going to prescribe (brand and pen or cartridge size), based on factors such as approved indications and dose limits for the product, suitability for the patient and patient preference. Note that not all products are approved for all indications or all age groups.

3. For somatropin, use the Dose Calculator, downloadable at https://www.pbs.gov.au/browse/section100-gh

   This also assists with providing the item code.

4. Write an authority script in conjunction with making an authority application, by either

   a. Real time application using the Online PBS Authorities system – highly recommended and preferred, or

   b. writing and use HPOS Form upload, or

   c. writing and mail to PBS Complex Drugs Programs.

Continuing Prescription Steps

1. Determine patient eligibility for ongoing treatment. This requires reference to or a knowledge of the PBS eligibility criteria.

2. Decide on any dose adjustment based on factors such as approved indications and dose limits for the product.

3. For somatropin, use the Dose Calculator, downloadable at https://www.pbs.gov.au/browse/section100-gh

   This also assists with providing the item code.

4. Write an authority script in conjunction with making an authority application, by either

   a. Real time application using the Online PBS Authorities system – highly recommended and preferred, or

   b. writing and use HPOS Form upload, or

   c. writing and mail to PBS Complex Drugs Programs.

5. Available products

Daily and Weekly Growth Hormone (Somatropin and Somatrogon)) Products

The following daily growth hormone (somatropin) and weekly growth hormone (somatrogon) brands and products are currently available in Australia. Note that not all products are available for all indications and ages groups.

This should be used in conjunction with the:

1. PBS listings for the specific drugs

   https://www.pbs.gov.au/pbs/home

2. Dose and cartridge quantity calculator for somatropin
   https://www.pbs.gov.au/browse/section100-gh, and

3. Somatrogon prescribed maximum quantity calculator by weight
   https://www.pbs.gov.au/browse/section100-gh

Table of available products – Somatropin and Somatrogon

Somatropin products	Cartridge/pen volume	Approved Indications	Storage / shelf life	Preservative
Genotropin Go Quick 5mg pens (Pfizer)	1ml	Paediatric: all Only product registered for PWS Mature skeleton and adult: documented childhood GHD, or severe GHD documented with mature skeleton or in an adult. Not subsidized for PWS > 18 years unless documented severe GHD or childhood GHD.	Store at 2-8 degrees C. Refrigerate, do not freeze. Protect from light. 28 days at 2-8 degrees C once reconstituted. Storage under 25 degrees C for 1 month is possible within the proposed shelf-life, prior to reconstitution.	Metacresol (3-methylphenol)
Genotropin Go Quick 12mg pens (Pfizer)	1ml	Paediatric: all Only product registered for PWS Mature skeleton and adult: documented childhood GHD, or severe GHD documented with mature skeleton or in an adult. Not subsidized for PWS > 18 years unless documented severe GHD or childhood GHD.	Store at 2-8 degrees C. Refrigerate, do not freeze. Protect from light. 28 days at 2-8 degrees C once reconstituted. Storage under 25 degrees C for 1 month is possible within the proposed shelf-life, prior to reconstitution.	Metacresol (3-methylphenol)
Genotropin MiniQuick single use syringes – 0.4mg, 0.6mg, 0.8mg, 1mg, 1.2mg, 1.4mg, 1.6mg, 1.8mg, 2mg	All 0.25ml	Paediatric: all Only product registered for PWS Mature skeleton and adult: documented childhood GHD, or severe GHD documented with mature skeleton or in an adult. Not subsidized for PWS > 18 years unless documented severe GHD or childhood GHD.	Store at 2-8 degrees C. Refrigerate, do not freeze. Protect from light. The reconstituted solution should be used immediately but can be stored at 2-8 degrees C protected from light for up to 24 hours.	Nil
Norditropin Flexpro 5mg prefilled pen (Novo Nordisk)	1.5ml	Paediatric: all, EXCEPT PWS Mature skeleton and adult: documented childhood GHD, or severe GHD documented with mature skeleton or in an adult.	Store in a refrigerator (2°C-8°C) in the outer carton, in order to protect from light. Do not store close to any cooling elements. Do not freeze. When in use, the product may be stored for a maximum of 28 days in a refrigerator (2°C-8°C), alternatively stored for a maximum of 21 days below 25°C.	Phenol

Somatropin products	Cartridge/pen volume	Approved Indications	Storage / shelf life	Preservative
Norditropin Flexpro 10mg prefilled pen (Novo Nordisk)	1.5ml	Paediatric: all, EXCEPT PWS	Store in a refrigerator (2°C-8°C) in the outer carton, in order to protect from light. Do not store close to any cooling elements. Do not freeze. When in use, the product may be stored for a maximum of 28 days in a refrigerator (2°C-8°C), alternatively stored for a maximum of 21 days below 25°C.	Phenol
Norditropin Flexpro 15mg prefilled pen (Novo Nordisk)	1.5ml	Paediatric: all, EXCEPT PWS	Store in refrigerator (2°C-8°C) in the outer carton, in order to protect from light. Do not store close to any cooling elements. Do not freeze. When in use, the product may be stored for a maximum of 28 days in a refrigerator (2°C-8°C), alternatively stored for a maximum of 21 days below 25°C.	Phenol
Omnitrope 5mg cartridge (Sandoz)	1.5ml	Paediatric: all, EXCEPT PWS NOT FOR CHILDREN UNDER 3 YEARS because of preservative	Store at 2°C to 8°C (in a refrigerator). Do not freeze. Store in the original package in order to protect from light.	Benzyl alcohol
Omnitrope 10mg cartridge (Sandoz)	1.5ml	Paediatric: all, EXCEPT PWS NOT FOR CHILDREN UNDER 3 YEARS because of preservative	Store at 2°C to 8°C (in a refrigerator). Do not freeze. Store in the original package in order to protect from light.	Benzyl alcohol
Omnitrope 10mg cartridge (Sandoz)	1.5ml	Paediatric: all, EXCEPT PWS NOT FOR CHILDREN UNDER 3 YEARS because of preservative	Store at 2°C to 8°C (in a refrigerator). Do not freeze. Store in the original package in order to protect from light.	Benzyl alcohol
Saizen 6mg cartridge (Merck)	1.03ml	Paediatric: all, EXCEPT PWS For CRI, only in pre-pubertal children Mature skeleton and adult: documented childhood GHD, or severe GHD documented with mature skeleton or in an adult.	Stored at 2°C to 8°C (refrigerate, do not freeze) in the original package in order to protect from light. After first injection, use within 28 days. After first injection, the Saizen cartridge in the autoinjector devices can be stored for up to 7 days at or below 25°C (outside a refrigerator). Following this, the Saizen cartridge must be returned to the refrigerator and stored at 2°C to 8°C and used within 28 days after the first injection.	Metacresol (3-methylphenol
Saizen 12mg cartridge (Merck)	1.5ml	Paediatric: all, EXCEPT PWS For CRI, only in pre-pubertal children Mature skeleton and adult: documented childhood GHD, or severe GHD documented with mature skeleton or in an adult.	Stored at 2°C to 8°C (refrigerate, do not freeze) in the original package in order to protect from light. After first injection, use within 28 days. After first injection, the Saizen cartridge in the autoinjector devices can be stored for up to 7 days at or below 25°C (outside a refrigerator). Following this, the Saizen cartridge must be returned to the refrigerator and stored at 2°C to 8°C and used within 28 days after the first injection.	Metacresol (3-methylphenol

Somatropin products	Cartridge/pen volume	Approved Indications	Storage / shelf life	Preservative
Saizen 20mg cartridge (Merck)	2.5ml	Paediatric: all, EXCEPT PWS For CRI, only in pre-pubertal children	Stored at 2°C to 8°C (refrigerate, do not freeze) in the original package in order to protect from light. After first injection, use within 28 days. After first injection, the Saizen cartridge in the autoinjector devices can be stored for up to 7 days at or below 25°C (outside a refrigerator). Following this, the Saizen cartridge must be returned to the refrigerator and stored at 2°C to 8°C and used within 28 days after the first injection.	Metacresol (3-methylphenol
SciTropin A 5mg cartridge (SciGen)	1.5ml	Paediatric: all, EXCEPT PWS NOT FOR CHILDREN UNDER 3 YEARS because of preservative	Store at 2°C to 8°C (in a refrigerator). Do not freeze. Store in the original package in order to protect from light.	Benzyl alcohol
SciTropin A 10mg cartridge (SciGen)	1.5ml	Paediatric: all, EXCEPT PWS	Store at 2°C to 8°C (in a refrigerator). Do not freeze. Store in the original package in order to protect from light.	Phenol (Note – different to 5mg SciTropin)

Somatrogon	Cartridge/pen volume	Indications	Storage / shelf life	Preservative
Ngenla 24mg prefilled pen (Pfizer)	1.2ml	Paediatric: SSSG, BGHD The efficacy and safety of Ngenla have not been established in patients under 3 years of age.	Store Ngenla at 2°C to 8°C (refrigerate, do not freeze). Store in the original carton and away from direct sunlight. Do not freeze Ngenla or expose Ngenla to heat. After first use, the pen can be stored for up to 28 days of use in a refrigerator (2°C to 8°C). Do not expose to temperatures above 32°C, or leave it at room temperature for more than two hours with each use. The same pre-filled pen should not be used more than 5 times.	Metacresol (3-methylphenol
Ngenla prefilled pen 60mg (Pfizer)	1.2ml	Paediatric: SSSG, BGHD The efficacy and safety of Ngenla have not been established in patients under 3 years of age.	Store Ngenla at 2°C to 8°C (refrigerate, do not freeze). Store in the original carton and away from direct sunlight. Do not freeze Ngenla or expose Ngenla to heat. After first use, the pen can be stored for up to 28 days of use in a refrigerator (2°C to 8°C). Do not expose to temperatures above 32°C, or leave it at room temperature for more than two hours with each use. The same pre-filled pen should not be used more than 5 times.	Metacresol (3-methylphenol

6. PBS eligibility criteria and dosing for the approved indications

Categories of PBS-Subsidised Growth Hormone Therapy

There are 11 separate categories under which application for subsidised GH growth hormone therapy can be made. An application is either for initial treatment, or continuing treatment. The PBS requirements are found under the PBS listing for each product by searching with the PBS code or drug name.

1. Short stature and slow growth (SSG)
2. Short stature associated with biochemical growth hormone deficiency
3. Growth retardation secondary to an intracranial lesion, or cranial irradiation
4. Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants
5. Biochemical growth hormone deficiency and precocious puberty
6. Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth
7. Short stature associated with Turner syndrome
8. Short stature due to short stature homeobox (SHOX) gene disorders
9. Short stature associated with chronic renal insufficiency
10. Short stature and poor body composition due to Prader-Willi syndrome - non-mature skeleton, or mature skeleton
11. Treatment of late onset growth hormone deficiency

For continuing treatment, there are also separate categories for:

1. Reclassification of diagnosis
2. Change of drug from daily GH to weekly GH or vice versa, and
3. Recommencement of GH after a period of cessation, where cessation was not due to non-response at maximal dose

General Paediatric Requirements

For all paediatric indications, the following conditions apply:

- Must be treated by a specialist or consultant physician in paediatric endocrinology or a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology
- must be undergoing treatment for the stated indication with only one growth hormone at any given time.
- 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.
- must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes.
- must not have an active tumour or evidence of tumour growth or activity.

- Bone age – must be < 15.5 years (males), < 13.5 years (females)
- For initial applications:
    - 12 months of recent height and weight measurements (2 measurements in a window of 10-14 months) or 6 months of recent growth data (2 measurements in a window of 4-8 months) for an older child (Male: chronological age ≥ 12.0 years or bone age ≥ 10.0 years; Female: chronological age ≥ 10.0 years or bone age ≥ 8.0 years.
    - PWS applications also required waist circumference.
    - most recent data must not be more than 3 months old at the time of application
    - bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less)
- For continuing applications
    - Growth data (height and weight) for the most recent 6 month treatment period (start and end, 4-8 month window). PWS applications also required waist circumference.
    - bone age result performed within the last 12 months (except if chronological age is 2.5 years or less)

For the mature skeleton / late onset severe growth hormone deficiency:

- Must be treated by an endocrinologist.

This indication encompasses 4 groups:

1. Onset of growth hormone deficiency secondary to organic hypothalamic or pituitary disease diagnosed at chronological age of 18 years or older.

   Must meet criteria for severe GHD:

    a. insulin tolerance test peak GH less than 2.5 micrograms per litre; OR
    b. arginine infusion test peak GH less than 0.4 micrograms per litre; OR
    c. glucagon provocation test peak GH less than 3 micrograms per litre; OR
        i. a chronological age of 18 years or older,
        ii. established hypothalamic-pituitary disease,
        iii. at least three documented pituitary hormone deficiencies,
        iv. an IGF-1 concentration lower than the sex- and age-specific lower limit of normal in a patient.

2. Onset of growth hormone deficiency diagnosed after skeletal maturity (bone age greater than or equal to 15.5 years in males or 13.5 years in females) and before chronological age of 18 years

   Must meet criteria for severe GHD:

    a. insulin tolerance test peak GH less than 2.5 micrograms per litre; OR
    b. arginine infusion test peak GH less than 0.4 micrograms per litre; OR
    c. glucagon provocation test peak GH less than 3 micrograms per litre; OR
        i. a chronological age of 18 years or older
        ii. established hypothalamic-pituitary disease
        iii. at least three documented pituitary hormone deficiencies,

iv. an IGF-1 concentration lower than the sex- and age-specific lower limit of normal in a patient.

3. Previously diagnosed childhood onset growth hormone deficiency and received PBS-subsidised treatment as a child – continuation of therapy with mature skeleton or > 18 years

    a. Patient must have previously received PBS-subsidised GH therapy under an initial treatment restriction applying to a previously documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause in a patient with a mature skeleton. Paediatric GHD criteria from the initial diagnosis apply to this category, **not** severe GHD criteria for adult / mature skeleton.

4. Previously diagnosed childhood onset growth hormone deficiency and received non-PBS subsidised treatment as a child

    Must meet criteria for severe GHD:

    a. insulin tolerance test peak GH less than 2.5 micrograms per litre; OR

    b. arginine infusion test peak GH less than 0.4 micrograms per litre; OR

    c. glucagon provocation test peak GH less than 3 micrograms per litre; OR

        i. a chronological age of 18 years or older,

        ii. established hypothalamic-pituitary disease,

        iii. at least three documented pituitary hormone deficiencies,

        iv. an IGF-1 concentration lower than the sex- and age-specific lower limit of normal in a patient.

In contrast to paediatric indications, the item codes for initial treatment and continuing treatment in this category are the same (reasons unclear).

For Primary – IGF-1 deficiency – Mecasermin - see section below

7. Somatropin Indications and Dose table; somatropin daily injections

Indication	Allowable Dose	Products available*	Dosage notes (from approved Product Information)
Short and slowly growing	Up to 7.5mg/m2/week in daily divided doses. Allowing for dose increments and rounding and the manufacturer's packaging, the calculator allows a maximum of 7.725mg/m2/week if needed (+3%).	Genotropin (Pfizer) Norditropin (Novo Nordisk) Saizen (Merck) Omnitrope (> 3 years age only) (Sandoz) Scitropin A (SciGen) *see table above for more details on the range of products	Previous dose recommendations were a dose range of 4.5-7.5 mg/m2/week. Prescribers may consider starting treatment at the lower end of this dose range and incrementing as needed. However, outcome data suggest that non-GHD children do not respond well to doses at the lower part of this range.
Short stature associated with biochemical growth hormone deficiency	Up to 7.5mg/m2/week in daily divided doses. Allowing for dose increments and rounding and the manufacturer's packaging, the calculator allows a maximum of 7.725mg/m2/week if needed (+3%).	Genotropin (Pfizer) Norditropin (Novo Nordisk) Saizen (Merck) Omnitrope (> 3 years age only) (Sandoz) Scitropin A (SciGen)	Previous dose recommendations were a dose range of 4.5-7.5 mg/m2/week. Prescribers may consider starting treatment at the lower end of this dose range and incrementing as needed. Truly GH deficient are likely to respond well to doses in the lower part of this range.
Growth retardation secondary to an intracranial lesion, or cranial irradiation	Up to 7.5mg/m2/week in daily divided doses. Allowing for dose increments and rounding and the manufacturer's packaging, the calculator allows a maximum of 7.725mg/m2/week if needed (+3%).	Genotropin (Pfizer) Norditropin (Novo Nordisk) Saizen (Merck) Omnitrope (> 3 years age only) (Sandoz) Scitropin A (SciGen)	Previous dose recommendations were a dose range of 4.5-7.5 mg/m2/week. Prescribers may consider starting treatment at the lower end of this dose range and incrementing as needed. Truly GH deficient are likely to respond well to doses in the lower part of this range.

Indication	Allowable Dose	Products available*	Dosage notes (from approved Product Information)
Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants	Up to 7.5mg/m2/week in daily divided doses. Allowing for dose increments and rounding and the manufacturer's packaging, the calculator allows a maximum of 7.725mg/m2/week if needed (+3%).	Genotropin (Pfizer) Norditropin (Novo Nordisk) Saizen (Merck) Omnitrope (> 3 years age only) (Sandoz) Scitropin A (SciGen)	Previous dose recommendations were a dose range of 4.5-7.5 mg/m2/week. Prescribers may consider starting treatment at the lower end of this dose range and incrementing as needed. Truly GH deficient are likely to respond well to doses in the lower part of this range.
Biochemical growth hormone deficiency and precocious puberty	Up to 7.5mg/m2/week in daily divided doses. Allowing for dose increments and rounding and the manufacturer's packaging, the calculator allows a maximum of 7.725mg/m2/week if needed (+3%).	Genotropin (Pfizer) Norditropin (Novo Nordisk) Saizen (Merck) Omnitrope (> 3 years age only) (Sandoz) Scitropin A (SciGen)	Previous dose recommendations were a dose range of 4.5-7.5 mg/m2/week. Prescribers may consider starting treatment at the lower end of this dose range and incrementing as needed. Truly GH deficient are likely to respond well to doses in the lower part of this range.
Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth	Up to 7.5mg/m2/week in daily divided dosed. Allowing for dose increments and rounding and the manufacturer's packaging, the calculator allows a maximum of 7.725mg/m2/week if needed (+3%).	Genotropin (Pfizer) Norditropin (Novo Nordisk) Saizen (Merck) Omnitrope (> 3 years age only) (Sandoz) Scitropin A (SciGen)	Previous dose recommendations were a dose range of 4.5-7.5 mg/m2/week. Prescribers may consider starting treatment at the lower end of this dose range and incrementing as needed. Truly GH deficient are likely to respond well to doses in the lower part of this range.
Short stature associated with Turner syndrome	Up to 9.5mg/m2/week in daily divided doses. Allowing for dose increments and rounding and the manufacturer's packaging, the calculator allows a maximum of 9.785mg/m2/week if needed (+3%).	Genotropin (Pfizer) Norditropin (Novo Nordisk) Saizen (Merck) Omnitrope (> 3 years age only) (Sandoz) Scitropin A (SciGen)	Evidence indicates that higher doses of GH are required in Turner syndrome – 9.5mg/m2/week is recommended

Indication	Allowable Dose	Products available*	Dosage notes (from approved Product Information)
Short stature due to short stature homeobox (SHOX) gene disorders	Up to 9.5mg/m2/week in daily divided doses. Allowing for dose increments and rounding and the manufacturer's packaging, the calculator allows a maximum of 9.785mg/m2/week if needed (+3%).	Genotropin (Pfizer) Norditropin (Novo Nordisk) Saizen (Merck) Omnitrope (> 3 years age only) (Sandoz) Scitropin A (SciGen)	Evidence indicates that higher doses of GH are required in SHOX disorders – 9.5mg/m2/week is recommended
Short stature associated with chronic renal insufficiency	Up to 9.5mg/m2/week in daily divided doses. Allowing for dose increments and rounding and the manufacturer's packaging, the calculator allows a maximum of 9.785mg/m2/week if needed (+3%).	Genotropin (Pfizer) Norditropin (Novo Nordisk) Saizen (Merck) Omnitrope (> 3 years age only) (Sandoz) Scitropin A (SciGen)	Evidence indicates that higher doses of GH are required in CRI – 9.5mg/m2/week is recommended
Short stature and poor body composition due to Prader-Willi syndrome - non-mature skeleton	Up to 7.5mg/m2/week in daily divided dosed. Allowing for dose increments and rounding and the manufacturer's packaging, the calculator allows a maximum of 7.725mg/m2/week if needed (+3%).	Genotropin (Pfizer)	BSA calculated using ideal body weight if BMI > 85th percentile for age and sex.
Short stature and poor body composition due to Prader-Willi syndrome - mature skeleton	0.04mg/kg/week (must not exceed 0.0412mg/kg/week)	Genotropin (Pfizer)	Use ideal body weight if BMI > 85th percentile for age and sex.

Indication	Allowable Dose	Products available*	Dosage notes (from approved Product Information)
Treatment of late onset growth hormone deficiency	There is no set dose range – dosing is according to patient need, usually in the range 0.15 to 1mg per day. See Dosage notes column.	Genotropin (Pfizer) Norditropin (Novo Nordisk) Saizen (Merck)	At the start of Saizen therapy, low doses of 0.15-0.3 mg are recommended, given as a daily subcutaneous injection. The dose should be titrated carefully guided by IGF-1 age adjusted normal values and on the basis of clinical effect and adverse events. The recommended final Saizen dose seldom exceeds 1.0 mg/day. In general, the lowest efficacious dose should be administered. With women showing an increasing IGF-1 sensitivity over time, dose adjustment may be required for women, especially for those on oral estrogen replacement. In older or overweight patients, lower doses may be necessary.
			Genotropin: The recommended dosage at the start of therapy is 0.04 mg/kg/week divided into 7 daily subcutaneous injections. This dose should be gradually increased according to individual patient requirements to a maximum of 0.08 mg/kg/week. Women may require higher doses than men. This means that there is a risk that women, especially those on oral oestrogen replacement may be under-treated. Dose titration is based on the development of side effects and determination of serum levels of insulin-like growth factor (IGF-1). Dose requirements may decline with increasing age. It is recommended that regular monitoring of growth rate and measurement of biochemical markers, such as IGF-1 levels, be undertaken to ensure adequate delivery of growth hormone and compliance with therapy.
			Norditropin: The dosage must be adjusted to the need of the individual patient. It is recommended to start treatment with a low dose of 0.15-0.3 mg/day and to increase the dosage gradually at monthly intervals based on clinical response. Serum insulin-like growth factor 1 (IGF-1) can be used to guide dose titration. Dose requirements decline with age. Maintenance dosages vary from patient to patient, but seldom exceeds 1.0 mg.

8. Somatrogon dose table; long-acing (weekly) growth hormone

Indication	Allowable Dose	Products available*	Dosage notes
Short and slowly growing	Up to 0.66mg/kg/week	Ngenla (Pfizer)	The recommended dose is 0.66 mg/kg body weight administered once weekly by subcutaneous (SC) injection. For patients switching from daily growth hormone products, weekly therapy with Ngenla may be initiated at a dose of 0.66 mg/kg/week on the day following their last daily injection. Regular monitoring of Insulin-like Growth Factor-1 (IGF-1) concentrations is recommended during treatment with Ngenla. When monitoring for IGF-1, samples should always be drawn 4 days after the prior dose. Ngenla dosage may be adjusted as necessary, based on growth velocity, body weight and serum insulin-like growth factor 1 (IGF-1) concentration. In patients whose blood IGF-1 concentrations exceed the mean reference value for their age and sex by more than 2 SDS, the dose of Ngenla should be reduced by 15%. More than one dose reduction may be required in some patients. Monitor growth rate closely during the first year of Ngenla treatment. If a patient's growth rate fails to increase in the first year, assess for treatment adherence and other causes of growth failure (e.g. hypothyroidism, undernutrition, advanced bone age) and consider discontinuation of Ngenla treatment. Administer Ngenla once weekly, on the same day each week, at any time of the day. The day of weekly administration can be changed if necessary, as long as the time between the two doses is at least 3 days (> 72 hours). After selecting a new dosing day, the once weekly dosing should be continued. If a dose is missed, administer Ngenla as soon as possible within 3 days after the missed dose. If more than 3 days have passed, skip the missed dose and administer the next dose on the regularly scheduled day. In each case, patients can then resume their regular once weekly dosing schedule. Refer to the Instructions for Use leaflet for complete administration instructions.
Short stature associated with biochemical growth hormone deficiency			See above. Long-acting GH preparations are not suitable for children and young infants prone to hypoglycaemia, as GH levels (as opposed to IGF-1 levels) may not be sufficiently sustained to assist in sustaining glucose levels.

9. PBS listings and Item Codes

How to find PBS Listings

The PBS listing provides the detailed information on eligibility criteria. The full PBS listings are not reproduced in full here and should be accessed from the original source documents. However, an abbreviated version of eligibility criteria for various treatment categories is included below.

The best way to find the PBS listing is to search for PBS and the PBS item code from the table below for the product you wish to prescribe.

E.g. For initial treatment with Saizen 6mg, search for "PBS Saizen 5822K". Then click on the red "Authority Required" for the desired item code and all of the details will come up.

Table of PBS Item Codes for Each Product and Indication

PBS Item Codes			
PAEDIATRIC INDICATIONS			
Product	**Initial treatment phases**	**Continuing treatment phases (both with and without reclassification)**	**Recommencement treatment phases (both with and without reclassification)**
DAILY SOMATROPIN PRODUCTS			
Genotropin GoQuick 5mg	9585L	10443P	10435F
Genotropin GoQuick 12mg	9586M	10431B	10426R
Genotropin MiniQuick 0.4mgx7	10902T	10891F	10908D
Genotropin MiniQuick 0.6mgx7	9628R	10456H	10477K
Genotropin MiniQuick 0.8mgx7	6313G	10479M	10463Q
Genotropin MiniQuick 1.0mgx7	6314H	10480N	10430Y
Genotropin MiniQuick 1.2mgx7	6315J	10453E	10457J
Genotropin MiniQuick 1.4mgx7	6316K	10488B	10434E
Genotropin MiniQuick 1.6mgx7	6317L	10454F	10498M
Genotropin MiniQuick 1.8mgx7	6318M	10500P	10501Q
Genotropin MiniQuick 2.0mgx7	6319N	10428W	10472E
Norditropin FlexPro 5mg	5818F	10432C	10467X
Norditropin FlexPro 10mg	5819G	10451C	10496K
Norditropin FlexPro 15mg	5820H	10449Y	10489C
Omnitrope SurePal 5mg	10518N	10507B	10512G
Omnitrope SurePal 10mg	10514J	10506Y	10519P
Omnitrope SurePal 15mg	10446T	10490D	10485W
Saizen Solution 6mg	5822K	10462P	10458K
Saizen Solution 12mg	5824M	10483R	10495J
Saizen Solution 20mg	3388H	10497L	10442N
SciTropin A 5mg	6476W	10427T	10484T
SciTropin A 10mg	6311E	10441M	10481P

LONG ACTING GH			
Somatrogon 24mg	13119L	13130C	
Somatrogon 60mg	13120M	13125T	
MATURE SKELETON GHD/ LATE ONSET GHD / ADULT GHD			
Genotropin GoQuick 5mg	11493X	11493X	
Genotropin GoQuick 12mg	11495B	11495B	
Norditropin Flexpro 5mg	11895C	11895C	
Saizen 6mg	13712Q	13712Q	
Saizen 12mg	13709M	13709M	
PRIMARY IGF-1 DEFICIENCY			
Mecasermin	13116H	13116H	

10. Summary / abbreviated version of eligibility criteria for various categories of GH treatment

(for more detail, please refer to complete PBS listings on-line)

Short stature and slow growth (SSG)

Treatment Phase: Initial treatment

Current **height at or below the 1st percentile** for age and sex,

AND

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

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

must not have a height ≥167.7 cm (males) or 155.0 cm (females)

AND

must not have maturational or constitutional delay in combination with an estimated mature height ≥ 160.1 cm (males) or 148.0 cm (females).

Treatment Phase: Continuing treatment

Must have previously received treatment under the PBS S100 Growth Hormone Program under the SSG category

AND

For the most recent treatment period (32 weeks initial, or 26 weeks continuing, whichever applies):

Must not have been on the maximum dose of 7.5mg/m2/week or greater);

OR

While on the maximum dose of 7.5mg/m2/week or greater must have achieved the 50th percentile HV for bone age and sex, or an increase in height SDS for chronological age and sex, or a minimum growth velocity of 4cm/year, or achieved and maintained mid parental height SDS

AND

Must not have a height ≥ 167.7cm (males) or 155.0cm (females).

Short stature associated with biochemical growth hormone deficiency (BGHD)

Treatment Phase: Initial treatment

Patient must have evidence of **biochemical growth hormone deficiency**, as evidenced by either of:

peak serum GH < 10 mU/L or ≤ 3.3 Ug/l in response to 2 pharmacological GH tests (e.g. arginine, clonidine, glucagon, insulin);

OR

peak serum GH < 10 mU/L or ≤ 3.3 Ug/l in response to 1 pharmacological and 1 physiological GH test (e.g. sleep, exercise);

OR

peak serum GH < 10 mU/L or ≤ 3.3 Ug/l in response to 1 GH test (pharmacological or physiological) 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

peak serum GH < 10 mU/L or ≤ 3.3 Ug/l in response to 1 GH test (pharmacological or physiological) and low plasma IGF-1 levels;

OR

peak serum GH < 10 mU/L or ≤ 3.3 Ug/l in response to 1 GH stimulation test (pharmacological or physiological) and low plasma IGFBP-3 levels,

AND

Height ≤ 1st percentile for age and sex;

OR

Height <25th percentile for age and sex and HV <25th percentile for bone age and sex (over a 12 months, or 6 months for an older child);

OR

Height <25th percentiles for age and sex and an annual HV ≤ 14 cm per year if CA is ≤2 years;

OR

Height <25th percentile for age and sex and an annual HV of ≤8 cm per year if BA or CA is ≤ 2.5 years,

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

Treatment Phase: Continuing treatment

Must have previously received treatment under the PBS S100 Growth Hormone Program under the BGHD category

AND

For the most recent treatment period (32 weeks initial, or 26 weeks continuing, whichever applies):

Must not have been on the maximum dose of 7.5mg/m2/week or greater);

OR

While on the maximum dose of 7.5mg/m2/week or greater must have achieved the 50th percentile HV for bone age and sex, or an increase in height SDS for chronological age and sex, or a minimum growth velocity of 4cm/year, or achieved and maintained mid parental height SDS

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Initial treatment

Clinical criteria:

- 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 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,

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category,

AND

- Patient must not have been on the maximum dose of 7.5mg/m^2/week or greater for the most recent treatment period (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/m^2/week or greater for the most recent treatment period (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/m^2/week or greater for the most recent treatment period (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/m^2/week or greater for the most recent treatment period (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/m^2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies),

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/ infants

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

Clinical criteria:

- Patient must have a chronological age of less than 2 years,

AND

- Patient must have a documented clinical risk of hypoglycaemia,

AND

- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency,

AND

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes,

AND

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

AND

- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category,

AND

- Patient must not have been on the maximum dose of 7.5mg/m^2/week or greater for the most recent treatment period (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/m^2/week or greater for the most recent treatment period (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/m^2/week or greater for the most recent treatment period (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/m^2/week or greater for the most recent treatment period (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/m^2/week or greater for 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.

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'.

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years,

AND

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 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 not have previously received treatment under the PBS S100 Growth Hormone Program,

AND

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

Treatment Phase: Continuing treatment

Clinical criteria:

Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category,

AND

Patient must not have been on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m2/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies),

AND

Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes,

AND

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

AND

Patient must be male and must not have a bone age of 15.5 years or more; OR

Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the National Health (Growth Hormone Program) Special Arrangement 2015 and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form;

AND

A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment;

AND

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

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 final adult height (in cm) of the patient's mother and father (where available);

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.

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

AND

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 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.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category,

AND

- Patient must not have been on the maximum dose of 7.5mg/m^2/week or greater for the most recent treatment period (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/m^2/week or greater for the most recent treatment period (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/m^2/week or greater for the most recent treatment period (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/m^2/week or greater for the most recent treatment period (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/m^2/week or greater for 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.

Short stature associated with Turner syndrome

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

Clinical criteria:

- 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.

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category,

AND

- Patient must not have been on the maximum dose of 9.5mg/m^2/week or greater for the most recent treatment period (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/m^2/week or greater for the most recent treatment period (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/m^2/week or greater for the most recent treatment period (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/m^2/week or greater for the most recent treatment period (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/m^2/week or greater for 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 bone age of 13.5 years or greater,

AND

- Patient must not have a height greater than or equal to 155.0 cm.

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Initial treatment

Clinical criteria:

- 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.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

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Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category,

AND

- Patient must not have been on the maximum dose of 9.5mg/m^2/week or greater for the most recent treatment period (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/m^2/week or greater for the most recent treatment period (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/m^2/week or greater for the most recent treatment period (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/m^2/week or greater for the most recent treatment period (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/m^2/week or greater for 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.

Short stature associated with chronic renal insufficiency

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m^2 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/1.73m^2 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.

Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category,

AND

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes,

AND

- Patient must not have been on the maximum dose of 9.5mg/m^2/week or greater for the most recent treatment period (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/m^2/week or greater for the most recent treatment period (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/m^2/week or greater for the most recent treatment period (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/m^2/week or greater for the most recent treatment period (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/m^2/week or greater for 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/1.73m^2,

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.

Note

If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m^2 prescribers should seek reclassification to the indication short stature and slow growth.

Short stature and poor body composition due to Prader-Willi syndrome – non-mature skeleton

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); OR
- Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist,

AND

- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with no sleep disorders identified; OR
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified which are not of sufficient severity to require treatment; OR
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified for which the patient is currently receiving ameliorative treatment,

AND

- Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height,

AND

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

The authority application must also include:

- Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome; OR

Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist

- 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

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and poor body composition due to Prader-Willi syndrome category,

AND

- Patient must have been re-evaluated via polysomnography for airway obstruction and apnoea during the initial 32 week treatment period and any sleep disorders identified that required treatment must have been addressed,

AND

- Patient must 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/m^2/week or greater for the most recent treatment 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/m^2/week or greater for the most recent treatment 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/m^2/week or greater for the most recent treatment 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 circumference while on the maximum dose of 7.5mg/m^2/week or greater for the most recent treatment 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/m^2/week or greater for the most recent treatment 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/m^2/week or greater for the

most recent treatment 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 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.

Treatment of late onset severe GH deficiency

Treatment Phase: Initial treatment of late onset growth hormone deficiency

Clinical criteria:

- Patient must have onset of growth hormone deficiency secondary to organic hypothalamic or pituitary disease diagnosed at chronological age of 18 years or older; OR
- Patient must have onset of growth hormone deficiency diagnosed after skeletal maturity (bone age greater than or equal to 15.5 years in males or 13.5 years in females) and before chronological age of 18 years,

AND

- Patient must have a diagnostic insulin tolerance test with maximum serum growth hormone (GH) less than 2.5 micrograms per litre; OR
- Patient must have a diagnostic arginine infusion test with maximum serum GH less than 0.4 micrograms per litre; OR
- Patient must have a diagnostic glucagon provocation test with maximum serum GH less than 3 micrograms per litre; OR
- Patient must have: (a) a chronological age of 18 years or older, (b) established hypothalamic-pituitary disease, (c) at least three documented pituitary hormone deficiencies, (d) an IGF-1 concentration lower than the sex- and age-specific lower limit of normal in a patient.

The authority application must be in writing and must include:

1. Details of the proposed prescription; AND
2. A completed Severe Growth Hormone Deficiency supporting information form; AND
3. If applicable, results of the growth hormone simulation testing, including the date of testing, the type of test performed, the peak growth hormone concentration, and laboratory reference range for age/gender.

Treatment Phase: Continuing treatment in a person with a mature skeleton or aged 18 years or older

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy with this drug for this condition under an initial treatment restriction applying to a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause in a patient with a mature skeleton; OR
- Patient must have previously received PBS-subsidised therapy with this drug for this condition under an initial treatment restriction applying to late onset of growth hormone deficiency secondary to organic hypothalamic or pituitary disease in a patient with chronological age of 18 years or older; OR
- Patient must have previously received PBS-subsidised therapy with this drug for this condition under an initial treatment restriction applying to late onset of growth hormone deficiency diagnosed after skeletal maturity (bone age greater than or equal to 15.5 years in males or 13.5 years in females) and before chronological age of 18 years.

Treatment Phase: Initial treatment of childhood onset growth hormone deficiency in a patient who has received PBS-subsidised treatment as a child

Treatment criteria:

- Must be treated by an endocrinologist.

Clinical criteria:

- Patient must have a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause,

AND

- Patient must have previously received PBS-subsidised treatment with this drug for this condition as a child.

Population criteria:

- Patient must have a mature skeleton.

Somatropin is not PBS-subsidised for patients with Prader-Willi syndrome aged 18 years or older without a documented childhood onset Growth Hormone Deficiency.

Treatment Phase: Initial treatment of childhood onset growth hormone deficiency in a patient who has received non-PBS subsidised treatment as a child

Treatment criteria:

- Must be treated by an endocrinologist.

Clinical criteria:

- Patient must have a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause,

AND

- Patient must have previously received non-PBS subsidised treatment with this drug for this condition as a child,

AND

- Patient must have current or historical evidence of an insulin tolerance test with maximum serum growth hormone (GH) less than 2.5 micrograms per litre; OR
- Patient must have current or historical evidence of an arginine infusion test with maximum serum GH less than 0.4 micrograms per litre; OR
- Patient must have current or historical evidence of a glucagon provocation test with maximum serum GH less than 3 micrograms per litre.

Population criteria:

- Patient must have a mature skeleton.

Somatropin is not PBS-subsidised for patients with Prader-Willi syndrome aged 18 years or older without a documented childhood onset Growth Hormone Deficiency.

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11. Mecasermin for Severe growth failure with primary insulin-like growth factor-1 deficiency

Mecasermin was approved by the TGA in 2019 and approved by the PBAC in 2022 as a pharmaceutical benefit for severe primary IGF-1 deficiency in children and adolescents aged 2-18 years. This is a very rare condition. Incelex is subject to additional monitoring in Australia

Recombinant IGF-1	Presentation	Indications	Storage / shelf life	Preservative
Mecasermin (Increlex)	Multi-dose 5 ml vial	For the long-term treatment of growth failure in children and adolescents from 2 to 18 years with severe primary insulin-like growth factor 1 deficiency (Primary IGFD).	Once opened, the medicinal product may be stored for a maximum of 30 days at 2°C to 8°C.	Benzyl alcohol

Medication	Indication	Allowable Dose	Products available*	Dosage notes
Mecasermin	Severe primary IGF-1 deficiency 2-18 years	0.04-0.12 mg/kg	Increlex (Ipsen)	The recommended starting dose of mecasermin is 0.04 mg/kg of body weight twice daily by subcutaneous injection. If no significant adverse reactions occur for at least one week, the dose may be raised in increments of 0.04 mg/kg to the maximum dose of 0.12 mg/kg given twice daily. In the clinical trials, optimal growth response was seen with doses between 0.08 mg/kg and 0.12 mg/kg twice daily. Lower doses were less effective. Higher doses were more often associated with hypoglycaemia. Doses greater than 0.12 mg/kg twice daily should not be exceeded as this may increase the risk of neoplasia. If the recommended dose is not tolerated by the patient, treatment with a lower dose can be considered. Treatment success should be evaluated based on height velocities. Treatment should continue until bone age demonstrates fusion of epiphysis.

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be caused by severe primary insulin-like growth factor-1 deficiency (IGFD), with IGFD deficiency for the purpose of PBS subsidy defined as a basal IGF-1 level (measured any time prior to initiating treatment with this drug) below the 2.5th percentile adjusted for each of: (i) age, (ii) gender,

AND

- The condition must have resulted in the patient experiencing short stature, with short stature for the purpose of PBS subsidy defined as the patient's height (measured any time prior to initiating treatment with this drug) being at least 3 standard deviations below the norm, adjusted for each of: (i) age, (ii) gender,

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),

AND

- The condition must not be caused by growth hormone deficiency,

AND

- Patient must have a bone age of less than 13.5 years (females); OR
- Patient must have a bone age of less than 15.5 years (males),

AND

- The condition must not be caused by secondary causes of IGFD - prior to initiating treatment with this drug, the treating physician has at least excluded each of the following: (i) malnutrition, (ii) hypopituitarism, (iii) hypothyroidism, (iv) medication side effects,

AND

- The treatment must not be in a patient with known epiphyseal closure/growth plate fusion (i.e. the patient is known to have ceased growing).

Treatment criteria:

- Must be treated by a paediatric endocrinologist; the authority application must be completed by this physician type; OR
- Must be treated by a paediatrician who has consulted the above mentioned specialist type; the authority application must be completed by this paediatrician.

Population criteria:

- Patient must be aged from 2 years up until their 18th birthday.

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 initial treatment authority application must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include the following:

1. Insulin-like growth factor-1 deficiency:
    a. State each of:
        i. the patient's most recent basal IGF-1 level measured (ng/mL),
        ii. the measurement date (dd/mm/yy),
        iii. the name of the pathology result provider;

2. Short stature:
    a. State the patient's height (cm);
3. Normal growth hormone levels:
    a. State the patient's most recent growth hormone level measurement (mcg/L) - this figure must be greater than 6.6 mcg/L;
4. Bone age: (where the patient has a chronological age of at least 2.5 years):
    a. State each of:
        i. the patient's bone age in numerical figures at the time when it was most recently determined,
        ii. the date (dd/mm/yy) of this determination that is within 12 months of this authority application;
5. The patient's weight (kg);
6. The prescribed dose (mg/kg) (between 0.04 to 0.12);
7. The number of vials rounded to the nearest whole number, to provide sufficient drug quantity for 30 days of treatment per dispensing - see the relevant 'NOTE' attached to this listing for guidance.
    a. Height, growth velocity and weight measurements must not be more than three months old at the time of application.
    b. If the application is submitted through HPOS form upload or mail, it must include:
        i. A completed authority prescription form; 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).

Note

The Centers for Disease Control and Prevention (U.S. Department of Health & Human Services) publishes Clinical Growth Charts which this restriction refers to. Both the 'length-for-age' (birth to 36 months) and 'stature-for-age' (children 2 years to 20 years) growth charts can be viewed, printed and reproduced via the following website link:

https://www.cdc.gov/growthcharts/clinical_charts.htm

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition,

AND

- Patient must have a bone age of less than 13.5 years (females); OR
- Patient must have a bone age of less than 15.5 years (males),

AND

- The treatment must not be in a patient with known epiphyseal closure/growth plate fusion (i.e. the patient is known to have ceased growing),

AND

- The condition must be responsive to this drug treatment as evidenced by each of: (i) patient is showing catch-up for height standard deviation score against Laron syndrome (growth hormone insensitivity

syndrome) growth charts, (ii) patient has a growth velocity of greater than 2 cm per year (extrapolated for time on treatment) at the time of this continuing authority application; OR

- The condition must be yet to respond to this drug treatment only for the reason of sub-optimal dosing.

Treatment criteria:

- Must be treated by a paediatric endocrinologist; the authority application must be completed by this physician type; OR
- Must be treated by a paediatrician who has consulted the above mentioned specialist type; the authority application must be completed by this paediatrician.

Population criteria:

- Patient must be aged from 2 years up until their 18th birthday.

The continuing treatment authority application 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) The patient's height (cm);
(2) Where this authority application seeks to continue treatment where there has been an inadequate response to treatment due to sub-optimal dosing, state each of:
    (i) the most recently prescribed dose (mg/kg) that resulted in an inadequate response;
    (ii) the dose (mg/kg) (between 0.04 to 0.12) that was/will be subsequently prescribed to address the inadequate response;
(3) The patient's weight (kg);
(4) The patient's growth velocity in response to the preceding supply of drug (cm/year; extrapolated for time on treatment);
(5) The number of vials rounded to the nearest whole number, to provide sufficient drug quantity for 30 days of treatment per dispensing - see the relevant 'NOTE' attached to this listing for guidance.
    (i) Height, growth velocity and weight measurements must not be more than three months old at the time of application.
    (ii) Document growth improvements in the patient's medical records.
    (iii) If the application is submitted through HPOS form upload or mail, it must include:
        - A completed authority prescription form; and
        - 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).

Note

Laron syndrome growth charts are those appearing in the following publication:

Laron Z, Lilos P, Klinger B. Growth Curves for Laron syndrome. **Arch Dis Child**. 1993;68(6):768-770.

This literature article can be accessed through the following website link:

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1029371