Australian Government
Department of Human Services

medicare

PBS

Growth Hormone Program – paediatric initial PBS authority application

When to use this form

Use this authority application form (this form) for **initial** Pharmaceutical Benefits Scheme (PBS) subsidised treatment under the section 100 Growth Hormone Program for a paediatric patient with one of the following conditions:

- short stature and slow growth (SSSG)
- short stature associated with biochemical growth hormone deficiency (BGHD)
- growth retardation secondary to an intracranial lesion or cranial irradiation (CL/CI)
- hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth (HO)
- neonate or infant at risk of hypoglycaemia secondary to growth hormone deficiency (N)
- biochemical growth hormone deficiency and precocious puberty (PP)
- short stature associated with Turner syndrome (TS)
- short stature due to short stature homeobox gene disorders (SHOX)
- short stature associated with chronic renal insufficiency (CR)
- short stature and poor body composition due to Prader-Willi syndrome (PW).

Important information

Initial applications to start PBS subsidised treatment must be in writing and must include sufficient supporting information to determine the patient's eligibility according to the PBS criteria.

The patient must be treated by a specialist or a consultant physician in paediatric endocrinology, or by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

Prescriptions for initial treatment with somatropin, should be written for a maximum of 32 weeks of treatment (16 weeks with up to 1 repeat).

Under no circumstances will phone approvals be granted for **initial** authority applications or for treatment that would otherwise extend the treatment period.

The information in this form is correct at the time of publishing and may be subject to change.

Further treatment

This form is ONLY for **initial** treatment.

Applications for:

- continuing treatment
- recommencement treatment
- continuing as a reclassified patient treatment, **or**
- recommencement as a reclassified patient treatment

must be made in writing and submitted to the Australian Government Department of Human Services (Human Services) for those patients who meet the criteria.

Treatment specifics

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**.

A younger child is defined as:

- a male with a chronological age of **less than 12 years** or a bone age of **less than 10 years**, **or**
- a female with a chronological age of **less than 10 years** or a bone age of **less than 8 years**.

Current data or the most recent data must not be more than **3 months** old at the time of application.

For more information

Go to **humanservices.gov.au/healthprofessionals**

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Patient's details

1 Medicare card number

[ ][ ][ ][ ][ ] – [ ][ ][ ][ ][ ][ ][ ][ ] – [ ] Ref no. [ ]

or

Department of Veterans' Affairs card number

2 Mr ☐ Miss ☐ Other

Family name

First given name

3 Date of birth

/ /

4 Biological sex

Male ☐

Female ☐

Prescriber's details

5 Prescriber number

6 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

Family name

First given name

7 Business phone number

( )

Alternative phone number

Fax number

( )

Dosage details

8 ☐ I have used the paediatric dose and cartridge quantity calculator available on the Department of Health's website

Somatropin brand requested

Form and strength

Number of vials/cartridges requested

Dose

mg/m^2/week

mg/kg/week

Note: The mg/kg/week details are only required for Prader-Willi patients who have reached skeletal maturity.

Conditions and criteria

To qualify for PBS authority approval, the following conditions must be met.

9 **The patient**:

☐ is being treated by a specialist or a consultant physician in paediatric endocrinology, or by a specialist or consultant in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology

and

☐ does not have diabetes mellitus

and

☐ does 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 for short stature homeobox (SHOX) patients only)

and

☐ does not have an active tumour or evidence of tumour growth or activity

and

☐ has not previously received treatment under the PBS section 100 Growth Hormone Program.

10 Conditions

Select the condition for which you are applying for treatment
Tick ONE only

- ☐ short stature and slow growth (SSSG) ▶ ***Go to 11***
- ☐ short stature associated with biochemical growth hormone deficiency (BGHD) ▶ ***Go to 13***
- ☐ growth retardation secondary to an intracranial lesion or cranial irradiation (CL/CI) ▶ ***Go to 14***
- ☐ hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth (HO) ▶ ***Go to 15***
- ☐ neonate or infant at risk of hypoglycaemia secondary to growth hormone deficiency (N) ▶ ***Go to 16***
- ☐ biochemical growth hormone deficiency and precocious puberty (PP) ▶ ***Go to 17***
- ☐ short stature associated with Turner syndrome (TS) ▶ ***Go to 18***
- ☐ short stature due to short stature homeobox (SHOX) gene disorders ▶ ***Go to 19***
- ☐ short stature associated with chronic renal insufficiency (CR) ▶ ***Go to 20***
- ☐ short stature and poor body composition due to Prader-Willi syndrome (PW). ▶ ***Go to 21***

11 Does the patient have maturational or constitutional delay?

No ☐ ▶ ***Go to 22 - Table 2***

Yes ☐

12 Is the patient a:

- male with an estimated mature height below 160.1 cm, **or**
- female with an estimated mature height below 148.0 cm?

No ☐ ▶ ***Ineligible***

Yes ☐ ▶ ***Go to 22 - Table 2***

13 The patient has:

☐ evidence of biochemical growth hormone deficiency

and

☐ biochemical growth hormone deficiency is not secondary to an intracranial lesion or cranial irradiation.

Patients with a current height:

- at or below the 1st percentile ▶ ***Go to 22 - Table 1***
- above the 1st percentile ▶ ***Go to 22 - Table 2***

14 The patient has:

☐ had an intracranial lesion

and

☐ received treatment for this and has undergone a 12 month period of observation following completion of treatment

Provide date of completion of all treatment

/ /

or

☐ received medical advice that it is unsafe to treat the intracranial lesion and has undergone a 12 month period of observation since the initial diagnosis of the lesion

Provide the date of diagnosis

/ /

or

☐ received cranial irradiation without having had an intracranial lesion and has undergone a 12 month period of observation following completion of treatment for which the cranial irradiation was received

Provide date of completion of treatment for the condition for which intracranial irradiation was received

/ /

and

☐ evidence of biochemical growth hormone deficiency.

Patients with a current height:

- at or below the 1st percentile ▶ ***Go to 22 - Table 1***
- above the 1st percentile ▶ ***Go to 22 - Table 2***

15 The patient has:

☐ a structural lesion that is not neoplastic

or

☐ a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion

Provide date of completion of **all** treatment

/ /

or

☐ had a structural lesion that is neoplastic and has received medical advice that it is unsafe to treat the lesion and has undergone a 12 month period of observation since initial diagnosis of the structural lesion

Provide the date of diagnosis

/ /

and

☐ evidence of biochemical growth hormone deficiency

and

☐ other hypothalamic/pituitary hormone deficits (includes Adrenocorticotropic Hormone (ACTH), Thyroid Stimulating Hormone (TSH), Gonadotropin Releasing Hormone (GnRH) and/or vasopressin/Antidiuretic Hormone (ADH) deficiencies)

and

☐ hypothalamic obesity. ▶ ***Go to 22 - Table 2***

16 The patient has:

☐ documented clinical risk of hypoglycaemia

and

☐ documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency.

▶ ***Go to 22 - Table 1***

17 The patient:

☐ is a male and commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes ≥ 4 mL) before the chronological age of 9 years

or

☐ is a female and commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years

or

☐ is a female and menarche occurred before the chronological age of 10 years

and

☐ has evidence of biochemical growth hormone deficiency

and

☐ is undergoing Gonadotrophin Releasing Hormone (GnRH) agonist therapy for pubertal suppression.

▶ ***Go to 22 – Table 3***

18 The patient:

☐ has diagnostic results consistent with TS – genetically proven defined as:

- ☐ a loss of whole X chromosome in all cells (45X)

or

- ☐ a loss of a whole X chromosome in some cells (mosaic 46XX/45X)

or

- ☐ 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.

▶ ***Go to 22 – Table 3***

19 The patient has:

☐ diagnostic results consistent with SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis

or

☐ 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 sex determining region Y (SRY) gene positive by Fluorescence in Situ Hybridization (FISH) study)

and

☐ has an appropriate plan of management in place for the patient's increased risk of gonadoblastoma.

▶ ***Go to 22 – Table 2***

20 The patient has:

☐ an estimated glomerular filtration rate (eGFR) < 30 mL/minute/1.73m^2 measured by creatinine clearance, excretion of radionuclides such as diethylene triamine pentaacetic acid (DTPA), or by the height/creatinine formula

and

☐ not undergone a renal transplant

or

☐ undergone a renal transplant and has undergone a 12 month period of observation following the transplant

Provide date of transplant

/ /

Patients with a current height:

- at or below the 1st percentile ▶ ***Go to 22 - Table 1***
- above the 1st percentile ▶ ***Go to 22 - Table 2***

21 The patient:

☐ has diagnostic results consistent with PW (the condition must be genetically proven)

or

☐ has a clinical diagnosis of PW, confirmed by a clinical geneticist

and

☐ has been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months

and

- ☐ has had no sleep disorders identified

or

- ☐ has had sleep disorders identified which are not of sufficient severity to require treatment

or

- ☐ has had sleep disorders identified for which the patient is currently receiving ameliorative treatment

and

☐ does **not** have uncontrolled morbid obesity, defined as a body weight > 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

The patient has a current bone age:

☐ below skeletal maturity

or

☐ at or above skeletal maturity

Note: Skeletal maturity is a male bone age ≥ 15.5 years of age, or a female bone age ≥ 13.5 years of age.

Date patient reached skeletal maturity

/ /

▶ ***Go to 22 – Table 4***

22 Complete the following table(s)

Table 1 – For all BGHD, CL/CI and CR patients with a current height at or below the 1st percentile and ALL N patients

	Date	Height (cm)	Weight (kg)
Recent data	/ /		

'**N**' category ▶ ***Go to 24***

All other categories ▶ ***Go to 23***

Table 2 – For all BGHD, CL/CI and CR patients with a current height above the 1st percentile, and ALL SSSG, SHOX and HO patients

	Date	Height (cm)	Weight (kg)
All patients – recent data	/ /		
Older child only – 6 month data	/ /		
Younger child only – 12 month data	/ /		

All categories ▶ ***Go to 23***

Table 3 – TS and PP patients

	Date	Height (cm)	Weight (kg)
All patients – recent data	/ /		
All patients – 6 month data	/ /		
Younger child only – 12 month data	/ /		

▶ ***Go to 23***

Table 4 – PW patients

	Date	Height (cm)	Weight (kg)	Waist circumference (cm)
Recent data	/ /			
6 month data	/ /			

▶ ***Go to 24***

23 Provide the following:

Note: All SSSG and TS patients must supply a bone age.

A bone age result performed within the last 12 months, if the patient's current chronological age is > 2.5 years

[ ] years [ ] months

Date

[/ /]

▶ ***Go to 24***

Checklist

24 The relevant attachments need to be provided with this form.

- ☐ The completed authority prescription form(s).
- ☐ Evidence of biochemical growth hormone deficiency (including the type of tests performed and peak growth hormone concentrations) if applicable.

Privacy notice

25 Personal information is protected by law (including the *Privacy Act 1988*) and is collected by the Australian Government Department of Human Services for the purposes of assessing and processing this authority application.

Personal information may be used by the department, or given to other parties where the individual has agreed to this, or where it is required or authorised by law (including for the purpose of research or conducting investigations).

More information about the way in which the department manages personal information, including our privacy policy, can be found at **humanservices.gov.au/privacy**

Prescriber's declaration

26 **I declare that**:

- I have provided the completed authority prescription form(s) and any relevant attachments as specified in the Pharmaceutical Benefits Scheme restriction.
- the information I have provided in this form is complete and correct.

I understand that:

- giving false or misleading information is a serious offence.

Prescriber's signature

On completion, print and sign by hand.

Date

/ /

Reset form Print form

Returning your form

You can return this form and any supporting documents:

- **Online**, upload this form, the authority prescription form(s) and any relevant attachments through Health Professional Online Services (HPOS) at **humanservices.gov.au/hpos**
- **By mail**, send this form, the authority prescription form(s) and any relevant attachments to:

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