Australian Government
Services Australia

medicare

PBS

Growth Hormone Program – paediatric continuing as a reclassified patient PBS authority application

You can apply for a growth hormone authority through the Online PBS Authorities system.

Access to the system can be through your upgraded clinical or prescribing software, or via the Health Professional Online Services (HPOS).

Visit **servicesaustralia.gov.au/hpwrittenauthoritydrugs** for more information.

When to use this form

Use this authority application form (this form) for **continuing** Pharmaceutical Benefits Scheme (PBS) subsidised treatment under the section 100 Growth Hormone Program for a paediatric patient who will be reclassified to 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

Authority applications 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 medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology, or by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

To ensure continuity of treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an authority application form is submitted to Services Australia **no later than 2 weeks prior** to the patient completing their current course of treatment.

Prescriptions for continuing treatment as a reclassified patient with somatropin, should be written for a maximum of 26 weeks of treatment (13 weeks with up to 1 repeat).

Under no circumstances will phone approvals be granted for **continuing as a reclassified** patient 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 **continuing as a reclassified** patient treatment.

Applications for:

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

must be made in writing and submitted to Services Australia 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 **servicesaustralia.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 Dose of somatropin administered to patient for the **previous** treatment period

[mg/m^2/week]

9 ☐ 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.

10 The patient:

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

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

☐ the patient has previously received treatment under the PBS subsidised Growth Hormone (GH) Program – provide date previous treatment commenced.

[/ /]

11 Previous patient treatment

The patient has previously received PBS subsidised growth hormone treatment for the following condition:

Tick one only

- ☐ 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)
- ☐ a 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 (SHOX) gene disorders
- ☐ short stature associated with chronic renal insufficiency (CR)
- ☐ short stature and poor body composition due to Prader-Willi syndrome (PW).

12 The patient is reclassifying to:

☐ SSSG, BGHD, CL/CI, HO, N, PP or PW

and

☐ treatment has not lapsed due to failure to respond to growth hormone at a dose of 7.5 mg/m^2/week or greater for the most recent treatment period

or

☐ treatment has lapsed due to failure to respond to growth hormone at a dose of 7.5 mg/m^2/week or greater for the most recent treatment period

due to

☐ a significant medical illness

or

☐ major surgery (for example, renal transplant)

or

☐ an adverse reaction to growth hormone

or

☐ non-compliance due to social/family problems

or

☐ TS, SHOX or CR

and

☐ treatment has not lapsed due to failure to respond to growth hormone at a dose of 9.5 mg/m^2/week or greater for the most recent treatment period

or

☐ treatment has lapsed due to failure to respond to growth hormone at a dose of 9.5 mg/m^2/week or greater for the most recent treatment period

due to

☐ a significant medical illness

or

☐ major surgery (for example, renal transplant)

or

☐ an adverse reaction to growth hormone

or

☐ non-compliance due to social/family problems.

13 Conditions

Select the condition for which you are applying for treatment

Tick one only

- ☐ SSSG ▶ ***Go to 14***
- ☐ BGHD ▶ ***Go to 15***
- ☐ CL/CI ▶ ***Go to 16***
- ☐ HO ▶ ***Go to 17***
- ☐ N ▶ ***Go to 18***
- ☐ PP ▶ ***Go to 19***
- ☐ TS ▶ ***Go to 20***
- ☐ SHOX ▶ ***Go to 21***
- ☐ CR ▶ ***Go to 22***
- ☐ PW ▶ ***Go to 23***

14 The patient has:

☐ **not** previously received treatment under the indication short stature due to chronic renal insufficiency

▶ ***Go to 24 - Table 2***

or

☐ previously received treatment under the indication short stature due to chronic renal insufficiency

and

☐ has undergone a renal transplant, and completed a 12 month period of observation following transplant and has an estimated glomerular filtration rate (eGFR) of ≥ 30 mL/minute/1.73m^2 measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula.

Date of transplant

/ /

▶ ***Go to 24 - Table 4***

15 The patient has:

☐ evidence of biochemical growth hormone deficiency

and

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

and

☐ **not** previously received treatment under the indication neonate or infant at risk of hypoglycaemia secondary to growth hormone deficiency

Patients with a height immediately prior to commencing treatment:

- at or below the 1st percentile ▶ ***Go to 24 - Table 1***
- above the 1st percentile ▶ ***Go to 24 - Table 2***

or

☐ previously received treatment under the indication neonate or infant at risk of hypoglycaemia secondary to growth hormone deficiency

and

☐ reached or surpassed a chronological age of 5 years.

▶ ***Go to 24 - Table 4***

16 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 height immediately prior to commencing treatment:

- at or below the 1st percentile Click to go to 24: Table 1
- above the 1st percentile. Click to go to 24: Table 2

17 The patient has:

☐ a structural lesion that is not neoplastic

or

☐ had 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

☐ 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. Click to go to 24: Table 2

18 The patient must have a chronological age of < 2 years and has:

☐ a documented clinical risk of hypoglycaemia

and

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

Click to go to 24: Table 4

19 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.

Click to go to 24: Table 4

20 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.

Click to go to 24: Table 3

21 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

☐ if the patient's condition is secondary to mixed gonadal dysgenesis, an appropriate plan of management in place for the patient's increased risk of gonadoblastoma.

Click to go to 24: Table 2

22 The patient has:

☐ an estimated glomerular filtration rate (eGFR) < 30 mL/ minute/1.73 m^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 a period of 12 months observation following the transplant

Provide date of transplant

/ /

Patients with a height immediately prior to commencing treatment:

- at or below the 1st percentile Go to 24: Table 1
- above the 1st percentile. Go to 24: Table 2

23 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 whilst on growth hormone treatment and any sleep disorders identified that required treatment have been addressed

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

/ /

Click to go to 24: Table 4

24 Complete the following table(s):

Table 1 – For all BGHD, CL/CI and CR patients with a height at or below the 1st percentile immediately prior to commencement (PTC) of GH treatment

	Date	Height (cm)	Weight (kg)
Data immediately PTC	/ /		
Data for the most recent 6 month course of treatment:			
Recent data (within 3 months)	/ /		
6 month data	/ /		

All categories **Go to 26**

Table 2 – For all BGHD, CL/CI and CR patients with a height above the 1st percentile immediately prior to commencement (PTC) of GH treatment AND all SSSG, SHOX and HO patients

	Date	Height (cm)	Weight (kg)
All patients – data immediately PTC	/ /		
Older child only – 6 month data PTC	/ /		
Younger child only – 12 month data PTC	/ /		
All patients – Data for the most recent 6 month course of treatment:			
Recent data (within 3 months)	/ /		
6 month data	/ /		

All categories **Go to 25**

Table 3 – TS patients

	Date	Height (cm)	Weight (kg)
Height data immediately PTC	/ /		(Not required PTC)
Data for the most recent 6 month course of treatment:			
Recent data (within 3 months)	/ /		
6 month data	/ /		

Go to 26

Table 4 – All N, PP and PW patients, AND all patients reclassifying to BGHD from N, AND all patients reclassifying to SSSG from CR

	Date	Height (cm)	Weight (kg)
Data for the most recent 6 month course of treatment:			
Recent data (within 3 months)	/ /		
6 month data	/ /		

PP patients AND all patients reclassifying to BGHD from N, AND all patients reclassifying to SSSG from CR categories **Go to 26**

PW and N categories **Go to 27**

25 Provide the following:

Note: All SSSG patients must supply a bone age.

A bone age result performed **within the 12 months immediately prior to commencement** of GH treatment, if the patient's chronological age was > 2.5 years.

_____ years _____ months

Date

/ /

26 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 26

Checklist

27 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

28 Personal information is protected by law (including the *Privacy Act 1988*) and is collected by Services Australia for the purposes of assessing and processing this authority application.

Personal information may be used by Services Australia, 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 Services Australia manages personal information, including our privacy policy, can be found at **servicesaustralia.gov.au/privacy**.

Prescriber's declaration

29 **I declare that**:

- I have provided the completed authority prescription form(s) and the 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 this form

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 **servicesaustralia.gov.au/hpos**
- by post, send this form, the authority prescription form(s) and any relevant attachments to:

  Services Australia
  Complex Drugs Programs
  Reply Paid 9826
  HOBART TAS 7001