Australian Government
Services Australia

medicare

PBS

Growth hormone paediatric – continuing authority application

Online PBS Authorities

Requesting PBS Authorities online provides an immediate assessment in real time.

For more information and how to access the **Online PBS Authorities** system, go to **servicesaustralia.gov.au/hppbsauthorities**

When to use this form

Use this form to apply for **continuing** PBS-subsidised somatrogon or somatropin under the section 100 Growth Hormone Program for patients with severe growth hormone deficiency.

Conditions eligible for PBS-subsidised **somatrogon**:

- short stature and slow growth (SSSG)
- short stature associated with biochemical growth hormone deficiency (BGHD).

Conditions eligible for PBS-subsidised **somatropin**:

- 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 an intracranial 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

Continuing applications can be made in real time using the **Online PBS Authorities** system, or in writing and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

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 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** authority applications.

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

Continuing and recommencing treatment

Applications for:

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

can be made in real time using the **Online PBS Authorities** system, or in writing and submitted to Services Australia for those patients who meet the criteria.

For more information

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

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Online PBS Authorities

You do not need to complete this form if you use the **Online PBS Authorities** system.

Go to **servicesaustralia.gov.au/hppbsauthorities**

Patient's details

1 Medicare card number

Ref no.

or

Department of Veterans' Affairs card number

2 Family name

First given name

3 Date of birth (DD MM YYYY)

4 Biological sex

Male

Female

Prescriber's details

5 Prescriber number

6 Family name

First given name

7 Business phone number (including area code)

Alternative phone number (including area code)

Dosage details

8 Dose of growth hormone administered to patient for the **previous** treatment period

somatrogon dose

mg/kg/week

or

somatropin dose

mg/m^2/week

or

somatropin dose (for Prader-Willi patients with a bone age at or above skeletal maturity only)

mg/kg/week

9 This application is for:

somatrogon (SSSG or BGHD only)

Combination of pens requested

of 60mg/1.2mL pen +

of 24mg/1.2mL pen

Dose

mg/kg/week

or

somatropin

I have used the growth hormone program dose and cartridge quantity calculator for SOMATROPIN ONLY available on the Department of Health and Aged Care website

Somatropin brand requested

Form and strength

Number of vials/cartridges requested

Dose

mg/m^2/week

mg/kg/week

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

MCA0PB163 2506

Conditions and criteria

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

10 The patient:

☐ 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

☐ is undergoing treatment for the stated indication with only one growth hormone at any given time

11 Criteria

This application is for treatment for:

☐ short stature and slow growth (SSSG)

and

☐ the patient has previously received PBS-subsidised growth hormone treatment with this drug for this condition

▶ ***Go to 12***

or

☐ short stature associated with biochemical growth hormone deficiency (BGHD)

and

☐ the patient has previously received PBS-subsidised growth hormone treatment with this drug for this condition

▶ ***Go to 12***

or

☐ growth retardation secondary to an intracranial lesion or cranial irradiation (CL/CI)

and

☐ the patient has previously received PBS-subsidised somatropin treatment for this condition

▶ ***Go to 12***

or

☐ hypothalamic-pituitary disease secondary to an intracranial lesion, with hypothalamic obesity driven growth (HO)

and

☐ the patient has previously received PBS-subsidised somatropin treatment for this condition

▶ ***Go to 12***

or

☐ neonate or infant at risk of hypoglycaemia secondary to growth hormone deficiency (N)

and

☐ the patient has previously received PBS-subsidised somatropin treatment for this condition

When a patient receiving treatment under this indication reaches or surpasses 5 chronological years of age, prescribers should seek reclassification to the indication short stature due to biochemical growth hormone deficiency using the appropriate reclassification application form.

▶ ***Go to 12***

or

☐ biochemical growth hormone deficiency and precocious puberty (PP)

and

☐ the patient has previously received PBS-subsidised somatropin treatment for this condition

▶ ***Go to 12***

or

☐ short stature associated with Turner syndrome (TS)

and

☐ the patient has previously received PBS-subsidised somatropin treatment for this condition

▶ ***Go to 12***

or

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

and

☐ the patient has previously received PBS-subsidised somatropin treatment for this condition

▶ ***Go to 12***

or

☐ short stature associated with chronic renal insufficiency (CR)

and

☐ the patient has previously received PBS-subsidised somatropin treatment for this condition

and

☐ the patient has not undergone a renal transplant within the 12 month period immediately prior to the date of application

and

☐ the patient does not have an estimated glomerular filtration rate (eGFR) ≥ 30 mL/minute/1.73 m^2

▶ ***Go to 12***

or

☐ short stature and poor body composition due to Prader-Willi syndrome (PW)

and

☐ the patient has previously received PBS-subsidised somatropin treatment for this condition

and

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

and

☐ the patient 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.

PW patients only: Maintenance of measures of response to treatment is defined as a value within a 5% tolerance (this allows for seasonal and other measurement variations).

▶ ***Go to 13***

12 Provide the following:

The most recent data **must not** be older than 3 months.

Current height (at the **end** of most recent treatment period)

cm

Date (DD MM YYYY)

Current weight (at the **end** of most recent treatment period)

kg

Date (DD MM YYYY)

Height 6 months ago (at the **start** of most recent treatment period)

cm

Date (DD MM YYYY)

Weight 6 months ago (at the **start** of most recent treatment period)

kg

Date (DD MM YYYY)

and

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

years months

Date of last bone age result (DD MM YYYY)

and if available (not required for Turner syndrome or Prader-Willi syndrome).

Father's height cm

Mother's height cm

▶ *Go to 14*

13 Provide the following:

The most recent data **must not** be older than 3 months.

Current height (at the **end** of most recent treatment period)

cm

Date (DD MM YYYY)

Current weight (at the **end** of most recent treatment period)

kg

Date (DD MM YYYY)

Height 6 months ago (at the **start** of most recent treatment period)

cm

Date (DD MM YYYY)

Weight 6 months ago (at the **start** of most recent treatment period)

kg

Date (DD MM YYYY)

Current waist circumference (at the **end** of most recent treatment period)

cm

Date (DD MM YYYY)

Waist circumference 6 months ago (at the **start** of most recent treatment period)

cm

Date (DD MM YYYY)

and

Has skeletal maturity been achieved?

No ☐

Yes ☐▶ Date that skeletal maturity was achieved (DD MM YYYY)

Checklist

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

☐ Details of the proposed prescription(s).

Privacy notice

15 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/privacypolicy**

Prescriber's declaration

You do not need to **sign** the declaration if you complete this form using Adobe Acrobat Reader and return this form through Health Professional Online Services (HPOS) at **servicesaustralia.gov.au/hpos**

16 I declare that:

- I am aware that this patient must meet the criteria listed in the current Schedule of Pharmaceutical Benefits to be eligible for this medicine
- I have informed the patient that their personal information (including health information) will be disclosed to Services Australia for the purposes of assessing and processing this authority application
- I have provided details of the proposed prescription(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.

☐ I have read, understood and agree to the above.

Date (DD MM YYYY) (you **must** date this declaration)

Prescriber's signature (**only** required if returning by post)

If returning by post, print and sign by hand.

Reset form

Returning this form

Return this form, details of the proposed prescription(s) and any relevant attachments:

- **online** (no signature required), upload through HPOS at **servicesaustralia.gov.au/hpos**

  or

- by post (signature required) to

  Services Australia
  Complex Drugs Programs
  Reply Paid 9826
  HOBART TAS 7001