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 somapacitan, somatrogon or somatropin under the section 100 Growth Hormone Program for patients with severe growth hormone deficiency.

Conditions eligible for PBS-subsidised **somapacitan** or **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, if requesting authority approval in writing, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment, and that an application is submitted to Services Australia at least 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 This application is for:

☐ **somapacitan** (SSSG or BGHD only)
only one of the two strengths below is prescribed at any given time

of 10 mg/1.5 mL pen

or

of 15 mg/1.5 mL pen

Dose

mg/kg/week

or

☐ **somatrogon** (SSSG or BGHD only)

Combination of pens requested

of 60 mg/1.2mL pen +

of 24 mg/1.2mL pen

Dose

mg/kg/week

or

☐ **somatropin**

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 2607

Conditions and criteria

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

9 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

10 Does the patient have diabetes mellitus?

Yes ☐ ***Go to 11***

No ☐ ***Go to 12***

11 Does the patient have adequate diabetes control, regular screening for diabetes complications, particularly retinopathy, and growth failure that is not due to poor diabetes control?

Yes ☐ ***Go to 12***

No ☐ ***Ineligible***

12 This application is to continue the treatment of one of the following conditions that the patient has previously received PBS-subsidised growth hormone treatment with this drug for:

☐ short stature and slow growth (SSSG)

Go to 13

or

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

Go to 13

or

☐ growth retardation secondary to an intracranial lesion or cranial irradiation (CLCI)

Go to 13

or

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

Go to 13

or

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

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 13

or

☐ biochemical growth hormone deficiency and precocious puberty (PP)

Go to 13

or

☐ short stature associated with Turner syndrome (TS)

Go to 13

or

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

Go to 13

or

☐ short stature associated with chronic renal insufficiency (CR)

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 13

or

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

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 14

13 For the most recent treatment period, the patient has:

☐ **not** been on the maximum dose

Provide the **previous** treatment dose

_____ mg/kg/week or

_____ mg/m^2/week

☐ achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose

☐ achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose

☐ achieved a minimum growth velocity of 4cm/year while on the maximum dose

☐ achieved and maintained mid parental height standard deviation score while on the maximum dose

☐ 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 (**Turner syndrome only**)

Go to 17

14 At the last application, had the patient achieved skeletal maturity?

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

▶ ***Go to 16***

No ☐ ▶ ***Go to 15***

15 For the most recent treatment period, the patient has:

☐ **not** been on the maximum dose

Provide the **previous** treatment dose

mg/m^2/week

☐ maintained or improved height percentile for age and sex while on the maximum dose

☐ maintained or improved body mass index SDS for age and sex while on the maximum dose

☐ maintained or improved waist circumference while on the maximum dose

☐ maintained or improved waist/height ratio (waist circumference in centimetres divided by height in centimetres) while on the maximum dose

☐ achieved an increase in height percentile with reference to the untreated Prader-Willi syndrome standards for age and sex while on the maximum dose

▶ ***Go to 18***

16 For the most recent treatment period, the patient has:

☐ **not** been on the maximum dose

Provide the **previous** treatment dose

mg/kg/week

☐ maintained or improved body mass index while on the maximum dose

☐ maintained or improved body mass index SDS for age and sex while on the maximum dose

☐ maintained or improved waist circumference while on the maximum dose

☐ maintained or improved waist/height ratio (waist circumference in centimetres divided by height in centimetres) while on the maximum dose

☐ maintained or improved weight SDS for age and sex while on the maximum dose

▶ ***Go to 18***

17 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).

Father's height cm

Mother's height cm

▶ ***Go to 19***

18 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)

Checklist

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

☐ Details of the proposed prescription(s).

Privacy notice

20 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**

21 **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**
- by post (signature required) to

  Services Australia
  Complex Drugs Programs
  Reply Paid 9826
  HOBART TAS 7001