Australian Government
Services Australia

medicare

PBS

Growth hormone paediatric – change or recommencement 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 **changing** or **recommencing** PBS-subsidised somapacitan, somatrogon or somatropin under the section 100 Growth Hormone Program for paediatric patients with severe growth hormone deficiency for one of the following conditions, and has previously received treatment for the same condition.

Conditions eligible for patients **changing** between PBS-subsidised **somapacitan**, **somatrogon** and **somatropin**:

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

Conditions eligible for patients **recommencing** PBS-subsidised **somapacitan** or **somatrogon** after a treatment break:

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

Conditions eligible for patients **recommencing** PBS-subsidised **somatropin** after a treatment break:

- 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)
- 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 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.

If recommencement of treatment is sought under a different indication to which the patient was previously receiving treatment, a **Growth hormone paediatric – recommencement as a reclassified patient authority application (PB166)** form should be submitted.

If a change of drug is sought under a different indication to which the patient was previously receiving treatment, the patient must first reclassify to the new indication before a change of drug authority application is submitted.

Prescriptions for change of drug or recommencement treatment 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 change or recommencement 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 continuing 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.

MCA0PB165 2607

Conditions and criteria

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

9 The patient:

☐ is **changing** treatment between PBS-subsidised somapacitan, somatrogon and somatropin for the same condition (**SSSG** or **BGHD** only)

and is being treated by a:

☐ specialist or consultant physician in paediatric endocrinology

or

☐ specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology

or

☐ is **recommencing** PBS-subsidised growth hormone treatment after a temporary break

and is being treated by a:

☐ medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology

or

☐ medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics

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

☐ 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 Select the condition to treat

Tick one only

☐ short stature and slow growth (SSSG)

or

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

or

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

or

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

or

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

or

☐ biochemical growth hormone deficiency and precocious puberty (PP)

and

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

or

☐ short stature associated with Turner syndrome (TS)

or

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

and the patient has 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

☐ 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 Hybridisation (FISH) study)

and

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

or

☐ short stature associated with chronic renal insufficiency (CR)

and

☐ the patient has an estimated glomerular filtration rate < 30 mL/minute/1.73m^2

and the patient:

☐ has not undergone a renal transplant

or

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

Date of transplant (DD MM YYYY)

☐☐ ☐☐ ☐☐☐☐

or

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

and

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

and

☐ the patient has not developed uncontrolled morbid obesity

13 The patient:

☐ has previously received PBS-subsidised growth hormone treatment for this condition

and

☐ is **changing** PBS-subsidised drug within the **same stated indication** (**SSSG** or **BGHD** only)

and

☐ has been treated with PBS-subsidised growth hormone for less than 32 weeks

or

☐ has been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment

or

☐ has been treated with PBS-subsidised growth hormone treatment for at least 32 weeks, with an inadequate response to treatment due to at least one of the following:

- ☐ a significant medical illness
- ☐ major surgery
- ☐ an adverse reaction to growth hormone
- ☐ non-compliance to treatment arising from social/ family problems
- ☐ sub-optimal dosing

▶ *Go to 14*

or

☐ is **recommencing** PBS-subsidised growth hormone treatment with the **same drug** for the **same stated indication** following a temporary treatment break

and

☐ had a lapse in treatment

and

☐ demonstrated an adequate response to treatment observed for the most recent treatment period

or

☐ did not have a lapse in treatment due to failure to respond to **somatropin** for SSSG, BGHD, CL/CI, HO, N or PP at a dose of at least 7.5 mg/m^2/week during the most recent treatment period

or

☐ did not have a lapse in treatment due to failure to respond to **somatropin** for TS, SHOX or CR at a dose of at least 9.5 mg/m^2/week during the most recent treatment period

or

☐ did not have a lapse in treatment due to failure to respond to **somatropin** for PW during the most recent treatment period at a dose of:

- ☐ at least 7.5 mg/m^2/week where bone age is below skeletal maturity
- ☐ at least 0.04 mg/kg/week where bone age is at or above skeletal maturity

or

☐ had a lapse in treatment as the response was affected by:

- ☐ a significant medical illness
- ☐ major surgery (e.g. renal transplant)
- ☐ an adverse reaction to growth hormone
- ☐ non-compliance due to social/family problems
- ☐ a lower than recommended dose (as specified in the approved Product Information – **somapacitan** and **somatrogon** only)

▶ *Go to 15*

14 Provide the following for the patient **changing** PBS-subsidised drug:

☐ growth data has been supplied within 3 months of this authority application

or

☐ growth data is supplied as below:

☐ Recent data (within 3 months)

Date (DD MM YYYY) ☐☐ ☐☐ ☐☐☐☐

Height ____ cm Weight ____ kg

and

☐ 6 month data

Date (DD MM YYYY) ☐☐ ☐☐ ☐☐☐☐

Height ____ cm Weight ____ kg

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 (DD MM YYYY) ☐☐ ☐☐ ☐☐☐☐

▶ *Go to 16*

15 Provide the following for the patient **recommencing** PBS-subsidised growth hormone treatment after a temporary break:

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

Current height ____ cm Date (DD MM YYYY) ☐☐ ☐☐ ☐☐☐☐

Current weight ____ kg Date (DD MM YYYY) ☐☐ ☐☐ ☐☐☐☐

Current waist circumference (PW only) ____ cm 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 (DD MM YYYY ☐☐ ☐☐ ☐☐☐☐

or

☐ PW patients **ONLY**, has skeletal maturity been achieved?

No ☐

Yes ☐ ▶ Date skeletal maturity was achieved

Date (DD MM YYYY) ☐☐ ☐☐ ☐☐☐☐

Checklist

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

☐ Details of the proposed prescription(s).

Privacy notice

17 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**

18 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.

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

Reset form