

Growth hormone paediatric – change or recommencement authority application

Online services



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 somatrogen 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 **somatrogen** and **somatropin**:

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

Conditions eligible for patients **recommencing** PBS-subsidised **somatrogen** 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, **and**
- 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



medicare



Growth hormone paediatric – change or recommencement authority application

Online services



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 Mr Miss Other

Family name

First given name

3 Date of birth (DD MM YYYY)

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 (including area code)

Alternative phone number (including area code)

Dosage details

8 This application is for:

somatogon (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/m²/week

mg/kg/week

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



MCA0PB165 2210

Conditions and criteria

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

9 The patient:

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

and

- is being treated by a specialist or 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

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 by a 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.

Criteria

10 Select the criteria for which you are applying for treatment

- 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 an intracranial 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 Gonadotropin 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 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

- 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/1.73 m²

and

has the patient had a renal transplant within the last 12 months?

No

Yes **Ineligible for GH treatment**

or

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

and

during the initial 32 week treatment 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.

11 The patient has:

previously received PBS-subsidised growth hormone treatment for this condition

and

is **changing** between PBS-subsidised somatogon and somatropin 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 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

or

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

and

had a lapse in treatment

and

not had a lapse in treatment due to failure to respond to **somatropin** for the treatment of SSSG, BGHD, CL/CI, HO, N or PP at a dose of 7.5 mg/m²/week or greater for the most recent treatment period

or

not had a lapse in treatment due to failure to respond to **somatropin** for the treatment of TS, SHOX or CR at a dose of 9.5 mg/m²/week or greater for the most recent treatment period

or

not had a lapse in treatment due to failure to respond to **somatropin** for treatment of PW at a dose of 7.5 mg/m²/week or greater for a patient with a bone age below skeletal maturity or at a dose of 0.04 mg/kg/week for a patient with a bone age at or above skeletal maturity for the most recent treatment period

or

response was affected by a significant medical illness

or

response was affected by major surgery (e.g. renal transplant)

or

response was affected by an adverse reaction to growth hormone

or

response was affected by non-compliance due to social/family problems

or

response was affected by a lower than recommended dose (as specified in the approved Product Information – **somatogon only**).

If the patient is changing treatment	▶ Go to 13
If the patient is recommencing treatment	▶ Go to 12

12 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	Date (DD MM YYYY)
<input type="text"/> cm	<input type="text"/> <input type="text"/> <input type="text"/>

Current weight	Date (DD MM YYYY)
<input type="text"/> kg	<input type="text"/> <input type="text"/> <input type="text"/>

Current waist circumference (PW only)	Date (DD MM YYYY)
<input type="text"/> cm	<input type="text"/> <input type="text"/> <input type="text"/>

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)
<input type="text"/> <input type="text"/> <input type="text"/>

▶ **Go to 14**

or

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

No

Yes Date skeletal maturity was achieved (DD MM YYYY)

▶ **Go to 14**

13 Provide the following for the patient **changing** between PBS-subsidised somatogron and somatropin:

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)

Checklist

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

The completed authority prescription form(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/privacy

Prescriber's declaration

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 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



Date (DD MM YYYY)

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 or
- 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