

Growth hormone paediatric – continuing as a reclassified patient 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, somatrogen or somatropin under the section 100 Growth Hormone Program for paediatric patients with severe growth hormone deficiency who will be **reclassified** to one of the following conditions.

Conditions eligible for reclassification for patients currently receiving PBS-subsidised **somapacitan** or **somatrogen**:

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

Conditions eligible for reclassification for patients currently receiving 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 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 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 authority application is submitted to Services Australia at least **2 weeks prior** to the patient completing their current course of treatment.

Prescriptions for continuing treatment as a reclassified patient 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. The information in this form is correct at the time of publishing and may be subject to change.

Continuing and recommencing treatment

This form is **ONLY** for **continuing as a reclassified** patient treatment.

Applications for:

- continuing treatment
- change or commencement treatment, **or**
- commencement 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.

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

medicare



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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

☐ **somatogon** (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/m²/week

mg/kg/week

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



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Conditions and criteria

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

9 The patient is being treated by a:

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

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

and

- ☐ has previously received treatment **with the same growth hormone** under the PBS-subsidised Growth Hormone (GH) program

Provide date previous treatment commenced (DD MM YYYY)

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11 Does the patient have diabetes mellitus?

Yes ☐ **Go to 12**

No ☐ **Go to 13**

12 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 13**

No ☐ **Ineligible**

13 Previous 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

and the patient is currently receiving PBS-subsidised:

- ☐ **somapacitan or somatrogen**

► **Go to 14**

- ☐ **somatropin**

► **Go to 15**

14 For a patient currently receiving PBS-subsidised somapacitan or somatrogen

- ☐ The patient is continuing treatment with PBS-subsidised somapacitan or somatrogen and reclassifying the condition to **SSSG** or **BGHD**

and

- ☐ there has been an adequate response to treatment observed for the most recent treatment period

or

- ☐ there has been an inadequate response to treatment observed for the most recent treatment period due to at least one of the following:

- ☐ a significant medical illness
- ☐ major surgery (for example, renal transplant)
- ☐ an adverse reaction to growth hormone
- ☐ non-compliance due to social/family problems
- ☐ a lower than recommended dose (as specified in the drug's approved Product Information)

► **Go to 16**

15 For a patient currently receiving PBS-subsidised somatropin

The patient is continuing treatment with PBS-subsidised somatropin and reclassifying the condition to:

- ☐ **SSSG, BGHD, CL/CI, HO, N, PP or PW**

and

- ☐ treatment has not lapsed due to failure to respond to somatropin at a dose of 7.5mg/m²/week for the most recent treatment period

or

- ☐ treatment has lapsed as the response was affected by:

- ☐ a significant medical illness
- ☐ major surgery (for example, renal transplant)
- ☐ an adverse reaction to growth hormone
- ☐ non-compliance due to social/family problems

or

- ☐ **TS, SHOX or CR**

and

- ☐ treatment has not lapsed due to failure to respond to somatropin at a dose of 7.5mg/m²/week for the most recent treatment period

or

- ☐ treatment has lapsed as the response was affected by:

- ☐ a significant medical illness
- ☐ major surgery (for example, renal transplant)
- ☐ an adverse reaction to growth hormone
- ☐ non-compliance due to social/family problems

16 Conditions

Select the condition the patient is being reclassified to

Tick one only

- ☐ SSSG ▶ **Go to 17**
- ☐ BGHD ▶ **Go to 18**
- ☐ CL/CI ▶ **Go to 20**
- ☐ HO ▶ **Go to 22**
- ☐ N ▶ **Go to 24**
- ☐ PP ▶ **Go to 25**
- ☐ TS ▶ **Go to 26**
- ☐ SHOX ▶ **Go to 27**
- ☐ CR ▶ **Go to 29**
- ☐ PW ▶ **Go to 31**

17 The patient:

- ☐ has 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/1.73m² measured by creatinine clearance, excretion of radionuclides such as diethylene triamine pentaacetic acid (DTPA), or by the height/creatinine formula.
- ▶ **Go to 32 - Table 4**

or

- ☐ has **not** previously received treatment under the indication short stature due to chronic renal insufficiency
and immediately prior to commencing treatment had:
 - ☐ a height at or below the 1st percentile for age and sex**and**
 - ☐ an annual growth velocity 8 cm per year or less and a bone or chronological age of 2.5 years or less
- ▶ **Go to 32 - Table 2**

or

- ☐ a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child)
- ▶ **Go to 32 - Table 2**

18 The patient has:

- ☐ evidence of biochemical growth hormone deficiency
and
 - ☐ biochemical growth hormone deficiency that 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
and a height immediately prior to commencing treatment:
 - ☐ at or below the 1st percentile for age and sex
- ▶ **Go to 32 - Table 1**
- or
- ☐ above the 1st and at or below the 25th percentile for age and sex
- ▶ **Go to 19**
- 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 32 - Table 4**

19 The patient has:

- ☐ an annual growth velocity of 14 cm per year or less and a chronological age of 2 years or less
- ▶ **Go to 32 - Table 2**
- or
- ☐ an annual growth velocity of 8 cm per year or less and a bone or chronological age of 2.5 years or less
- ▶ **Go to 32 - Table 2**
- or
- ☐ a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child)
- ▶ **Go to 32 - Table 2**

20 The patient has:

- ☐ had an intracranial lesion and is under appropriate observation and management
- or
- ☐ received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management
- and**
- ☐ evidence of biochemical growth hormone deficiency
and a height immediately prior to commencing treatment:
 - ☐ at or below the 1st percentile for age and sex
- ▶ **Go to 32 - Table 1**
- or
- ☐ above the 1st percentile for age and sex
- ▶ **Go to 21**

- 21** Immediately prior to commencing treatment, the patient had:
- ☐ an annual growth velocity of 14 cm per year or less and a chronological age of 2 years or less
- ▶ **Go to 32 - Table 2**
- or**
- ☐ an annual growth velocity of 8 cm per year or less and a bone or chronological age of 2.5 years or less
- ▶ **Go to 32 - Table 2**
- or**
- ☐ a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child)
- ▶ **Go to 32 - Table 2**

- 22** 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 (DD MM YYYY)
- | | | | | | | | | | |
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- 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 (DD MM YYYY)
- | | | | | | | | | | |
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- and**
- ☐ evidence of biochemical growth hormone deficiency
- and**
- ☐ other hypothalamic/pituitary hormone deficits (includes Adrenocorticotrophic Hormone (ACTH), Thyroid Stimulating Hormone (TSH), Gonadotrophin Releasing Hormone (GnRH) and/or vasopressin/Antidiuretic Hormone (ADH) deficiencies
- and**
- ☐ hypothalamic obesity

- 23** Immediately prior to commencing treatment, the patient had:
- ☐ an annual growth velocity of greater than 14 cm per year and a chronological age of 2 years or less
- ▶ **Go to 32 - Table 2**
- or**
- ☐ an annual growth velocity of greater than 8 cm per year and a bone or chronological age of 2.5 years or less
- ▶ **Go to 32 - Table 2**
- or**
- ☐ a growth velocity above the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child)
- ▶ **Go to 32 - Table 2**

- 24** The patient has:
- ☐ a chronological age of < 2 years
- and**
- ☐ a documented risk of hypoglycaemia
- and**
- ☐ documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency
- ▶ **Go to 32 - Table 4**
- 25** 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 GnRH agonist therapy for pubertal suppression
- ▶ **Go to 32 - Table 4**
- 26** 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
- ▶ **Go to 32 - Table 3**
- 27** 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

28 Immediately prior to commencing treatment, the patient had:

☐ a height at or below the 1st percentile for age and sex

and

☐ an annual growth velocity of 14 cm per year or less and a chronological age of 2 years or less

► **Go to 32 - Table 2**

or

☐ an annual growth velocity of 8 cm per year or less and a bone or chronological age of 2.5 years or less

► **Go to 32 - Table 2**

or

☐ a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child)

► **Go to 32 - Table 2**

29 The patient has:

☐ an eGFR < 30 mL/minute/1.73m² measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula

and

☐ not undergone a renal transplant

or

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

Provide the date of transplant (DD MM YYYY)

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and a height immediately prior to commencing treatment:

☐ at or below the 1st percentile for age and sex

► **Go to 32 - Table 1**

or

☐ above the 1st and at or below the 25th percentiles for age and sex

► **Go to 30**

30 Immediately prior to commencement of treatment, the patient had:

☐ an annual growth velocity of 14 cm per year or less and a chronological age of 2 years or less

► **Go to 32 - Table 2**

or

☐ an annual growth velocity of 8 cm per year or less and a bone or chronological age of 2.5 years or less

► **Go to 32 - Table 2**

or

☐ a growth velocity less than or equal to the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child)

► **Go to 32 - Table 2**

31 The patient:

☐ has diagnostic results consistent with PW and the condition is 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 has a current bone age:

☐ below skeletal maturity

or

☐ at or above skeletal maturity

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 (DD MM YYYY)

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► **Go to 32 - Table 4**

32 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 (DD MM YYYY)				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 34**

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 (DD MM YYYY)				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 33**

Table 3 – TS patients

	Date (DD MM YYYY)				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 34**

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 (DD MM YYYY)			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 34**

PW and N categories ► **Go to 35**

33 Provide the following:

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 (DD MM YYYY)

34 Provide the following:

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

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

- ☐ Details of the proposed prescription(s).
- ☐ Evidence of biochemical growth hormone deficiency (including the type of tests performed and peak growth hormone concentrations) if applicable.

Privacy notice

36 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 servicessaustralia.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 servicessaustralia.gov.au/hpos

37 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)

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



Returning this form

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

- **online** (no signature required), upload through HPOS at servicessaustralia.gov.au/hpos
- by post (signature required) to
Services Australia
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001