Australian Government
Services Australia

medicare

PBS

Growth hormone paediatric – recommencement 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 **recommencing** PBS-subsidised somapacitan, somatrogon or somatropin under the section 100 Growth Hormone Program for paediatric patients with severe growth hormone deficiency who will be **reclassified**.

Conditions eligible for reclassification 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 reclassification 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 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.

Prescriptions for recommencement treatment as a reclassified patient 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 **recommencement 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 **recommencement as a reclassified** patient treatment.

Applications for:

- continuing treatment
- change or recommencement treatment, **or**
- continuing 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**

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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.

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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 had a lapse in growth hormone treatment

and

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

  Provide date previous treatment commenced (DD MM YYYY)

  ☐☐ ☐☐ ☐☐☐☐

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 (PW)

and the patient is recommencing with:

- ☐ **somapacitan** or **somatrogon** ▶ ***Go to 14***
- ☐ **somatropin** ▶ ***Go to 15***

14 For a patient whose most recent PBS-subsidised treatment was with somapacitan or somatrogon

- ☐ The patient is recommencing treatment with PBS-subsidised somapacitan or somatrogon following a temporary break 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 whose most recent PBS-subsidised treatment was with somatropin

- ☐ The patient is recommencing treatment with PBS-subsidised somatropin following a temporary break 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 at least 7.5 mg/m^2/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 at least 9.5 mg/m^2/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/1.73m^2 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)

☐☐ ☐☐ ☐☐☐☐

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)

☐☐ ☐☐ ☐☐☐☐

and

☐ evidence of biochemical growth hormone deficiency

and

☐ other hypothalamic/pituitary hormone deficits (includes Adrenocorticotropic 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 Gonadotrophin Releasing Hormone (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/1.73m^2 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 has undergone a 12 month period of observation following the transplant

Provide the date of transplant (DD MM YYYY)

☐☐ ☐☐ ☐☐☐☐

and a height immediately prior to commencing treatment:

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

▶ ***Go to 32 - Table 1***

☐ 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)

☐☐ ☐☐ ☐☐☐☐

▶ ***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			
Recent data (within 3 months)			

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 – Recent data (within 3 months)			

All categories ▶ ***Go to 33***

Table 3 – TS patients

	Date (DD MM YYYY)	Height (cm)	Weight (kg)
Height data immediately PTC			(Not required PTC)
Recent data (within 3 months)			

▶ ***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)
Recent data (within 3 months)			

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 **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**

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)

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