

Growth hormone paediatric – somapacitan or somatrogen – initial grandfather 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 **initial grandfather** PBS-subsidised somapacitan or somatrogen under the section 100 Growth Hormone Program for paediatric patients who have received non-PBS-subsidised treatment with **somapacitan** or **somatrogen** for one of the following conditions:

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

Important information

Initial grandfather applications to start PBS-subsidised treatment 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.

Under no circumstances will phone approvals be granted for **initial grandfather** 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 initial grandfather treatment. Subsidy through this treatment phase must occur once per lifetime.

Applications for:

- continuing treatment
- continuing as a reclassified patient treatment
- change or recommencement 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.

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 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 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

☐ **somatrogen**

Combination of somatrogen pens requested

of 60 mg/1.2mL pen +

of 24 mg/1.2mL pen

Dose

mg/kg/week

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:

☐ is undergoing treatment for the stated indication with only
one growth hormone at any given time

and

☐ does not have a condition with a known risk of malignancy
including chromosomal abnormalities such as Down and
Bloom syndromes

and

☐ does not have an active tumour or evidence of tumour
growth or activity



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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 Is the patient undergoing privately funded treatment (e.g. through a clinical trial, a sponsor compassionate access program, supply from an overseas jurisdiction) with the requested drug at the time of this authority application?

Yes ☐

No ☐ **Ineligible**

14 The patient has demonstrated an:

☐ adequate response to non-PBS-subsidised treatment

or

☐ inadequate response to the most recent supply of non-PBS-subsidised treatment due to at least one of the following:

☐ 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 (as specified by the requested drug's approved Product Information) dose

15 The application is for the treatment of:

☐ short stature and slow growth (**SSSG**)

and

☐ the patient had a height no higher than the 1st percentile for age plus sex at the time treatment first commenced

and immediately prior to commencing treatment, the patient had:

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

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 17 - Table 2**

or

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

and

☐ the patient has evidence of biochemical growth hormone deficiency (attached with this authority application)

and

☐ the patient's biochemical growth deficiency is not secondary to an intracranial lesion or cranial irradiation

and immediately prior to commencing treatment, the patient had a height:

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

► **Go to 17 - Table 1**

or

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

► **Go to 16**

16 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 17 - Table 2**

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

► **Go to 17 - Table 2**

☐ 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 17 - Table 2**

17 Complete the following table(s):

Table 1 – for BGHD patients with a height at or below the 1st percentile immediately prior to commencement (PTC) of non-PBS-subsidised 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						

► Go to 19

Table 2 – for BGHD patients with a height above the 1st and at or below the 25th percentiles immediately prior to commencement (PTC) of non-PBS-subsidised treatment AND all SSSG 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						

► Go to 18

18 Provide the following:

A bone age result performed **within the 12 months immediately prior to commencement** of non-PBS-subsidised treatment, if the patient's chronological age was > 2.5 years.

years months

Date (DD MM YYYY)

19 Provide the following:

A bone age result performed **within the last 12 months**, if the patient's chronological age is > 2.5 years.

years months

Date (DD MM YYYY)

Checklist

20  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

21 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

22 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