



Pharmaceutical Benefits Scheme (PBS) section 100 Growth Hormone Program (somatropin)

May 2025

The Growth Hormone Program, established under section 100 of the *National Health Act 1953*, provides subsidised access to growth hormone for eligible paediatric and adult patients through the PBS.

What is the definition of an adult and a child for the purposes of prescribing growth hormone?

Different restriction criteria apply to the writing of a prescription for growth hormone for adults and children respectively. Prescribers should ensure the appropriate restriction criteria are met at the time of prescribing.

An adult means a person, who:

- is not a child or
- is 18 years of age or older and has late onset growth hormone deficiency.

A child means a person, who:

- has a non-mature skeleton or
- has as a diagnosis of Prader-Willi syndrome, with a mature skeleton and is less than 18 years of age.

The restriction criteria for the PBS supply of somatropin are available on the [PBS website](#).

Who is eligible to prescribe growth hormone?

For treatment in adults, somatropin pharmaceutical benefits must be prescribed by a specialist or consultant physician in endocrinology.

For:

- initial treatment in children, somatropin pharmaceutical benefits must be prescribed by a specialist or consultant physician in paediatric endocrinology or a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology;
- continuing treatment in children, somatropin pharmaceutical benefits must be prescribed by a medical practitioner; and

- for recommencement of treatment (including as a reclassified patient) and continuing treatment as a reclassified patient in children, somatropin pharmaceutical benefits must be prescribed by a medical practitioner in consultation with a nominated specialist, consultant physician in paediatric endocrinology, or consultant physician in general paediatrics.

What results are required to support an authority application for growth hormone for adults?

The relevant restriction criteria outline the testing requirements necessary to support an application for authority to prescribe growth hormone for adults.

Accepted stimulation tests and their applicable result thresholds include:

- a) current or historical evidence of a diagnostic insulin tolerance test with maximum serum growth hormone (GH) less than 2.5 micrograms per litre or
- b) current or historical evidence of a diagnostic arginine infusion test with maximum serum GH less than 0.4 micrograms per litre or
- c) current or historical evidence of a diagnostic glucagon provocation test with maximum serum GH less than 3 micrograms per litre.

Patients with childhood onset growth hormone deficiency (CO-GHD) due to a congenital, genetic or structural cause who have previously received PBS subsidised growth hormone therapy as children are not required to provide the results of growth hormone stimulation testing to meet the eligibility criteria for access to adult-use somatropin on the basis that evidence of growth hormone deficiency would have been provided in childhood.

What if my patient has previously received non-PBS subsidised treatment with somatropin as a child and wishes to access PBS subsidised treatment as an adult?

The PBS listing of somatropin for adult patients includes provisions to grandfather patients who have previously received non-PBS subsidised treatment with somatropin as a child. Patients in this category must demonstrate that they met all the initial PBS restriction criteria prior to initiating their non-PBS subsidised treatment. A grandfathered patient may qualify for PBS subsidised treatment under the relevant initial restriction once only. For continuing PBS subsidised treatment, a grandfathered patient must qualify under the restriction criteria for continuing treatment.

How do I submit an authority application?

Written Authority application forms for authority to prescribe growth hormone are available on the [Services Australia website](#).

Applications for authority to prescribe growth hormone can also be made in real time using the [Online PBS Authorities](#) system. For more information visit one of the following Services Australia webpages:

- [Growth hormone deficiency – paediatric patients](#); or
- [Growth hormone deficiency – childhood onset or late onset](#).

Any queries regarding prescribing arrangements may be directed to Services Australia on 1800 700 270 (hours of operation: 8am to 5pm local time, Monday to Friday).

Do I need to send supporting evidence with the application?

Supporting evidence will be requested in the authority application form consistent with the relevant PBS restriction requirements. Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

What will the application processing time be?

For online applications made through the [Online PBS Authorities](#) system, the assessment is made and returned in real time. Online authority applications can be submitted 24 hours a day, 7 days a week.

For written applications, Services Australia will generally process applications in order of receipt and processing will be completed as soon as possible. As an estimate, please allow at least two weeks for Services Australia to process the application once it has been received.

Prescribers submitting authority applications by post will also need to factor in the time required for the application to be received by Services Australia and the time it will take for the approved Authority prescription to be returned to the prescriber or the patient (or the patient's representative).

Prescribers also need to be aware that once the patient presents the approved Authority prescription to a pharmacy, time will be required for the pharmacy to order the supply of growth hormone and for it to be delivered to that pharmacy.

To ensure continuity of treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is submitted to Services Australia at least 2 weeks prior to the patient completing their current course of treatment.

Can prescriptions be written for brand-specific growth hormone medicines?

Yes. For both adult and paediatric growth hormone prescriptions, prescribers must specify on the Authority prescription the active ingredient name as well as the form, strength and brand of growth hormone being prescribed to the patient.

The same brand (in the same form and strength) must be dispensed for both the original and the repeat supplies. If the brand needs to be changed during the treatment period, this will require a separate authority approval from Services Australia.

How do I calculate the patient dose and number of cartridges required?

The prescriber is responsible for calculating each patient's weekly dose of growth hormone and the number of cartridges of the relevant product required for the treatment period. Please refer to the relevant product information for information on indication, usage, dosage and administration.

The Paediatric Dose and Cartridge Quantity Calculator for somatropin is available on the [PBS website](#).

Where can adult patients with childhood onset growth hormone deficiency (CO-GHD) due to a congenital, genetic or structural cause access PBS subsidised growth hormone?

Adult patients with CO-GHD due to a congenital, genetic or structural cause are able to access PBS subsidised growth hormone through community, public or private hospital pharmacies if they meet the relevant PBS restriction criteria. The usual PBS co-payment will apply for each dispensing of growth hormone.

Patients with CO-GHD due to a congenital, genetic or structural cause are eligible for access to adult-use somatropin – If they meet the relevant PBS restriction criteria – once they no longer meet the PBS restriction criteria for paediatric growth hormone treatment.

The majority of patients with CO-GHD due to a congenital, genetic or structural cause are eligible to access somatropin as adults once skeletal maturity is reached, rather than at the age of 18 years.

Patients with Prader-Willi Syndrome are eligible for access to adult-use somatropin at the age of 18 years or over.

Patients with CO-GHD due to a congenital, genetic or structural cause who have previously received PBS subsidised growth hormone therapy as children are not required to provide the results of stimulation testing to meet the eligibility criteria for adult-use somatropin.

What needs to be done if growth hormone supplies are compromised?

If a patient's growth hormone supply is compromised, either at home or at the pharmacy, prescribers should contact Services Australia for information about obtaining a new authority approval.

Who is responsible for ordering consumables?

Growth hormone consumables are not PBS items. Clinics/prescribers should liaise with the relevant pharmaceutical company to discuss arrangements for patients to obtain consumables.

Can growth hormone prescriptions written for patients of NSW and ACT public hospital clinics be dispensed under the PBS?

Growth hormone prescriptions written for patients of NSW and ACT public hospital clinics cannot be dispensed under the PBS, as these jurisdictions do not participate in the Pharmaceutical Reforms (i.e., Pharmaceutical Reform Agreements are not in place between the Commonwealth and these jurisdictions).