## PBS Growth Hormone Program

The Australian Government provides subsidised access to growth hormone for eligible paediatric and adult patients through the Pharmaceutical Benefits Scheme (PBS) Growth Hormone Program established under section 100 of the *National Health Act 1953*.

**Paediatric Listing of Mecasermin**

The PBAC recommended the listing of mecasermin for the long-term treatment of growth failure in children and adolescents from 2 years to 18 years with severe primary insulin-like growth factor 1 deficiency (Primary IGFD). This is a genetic condition. Mecasermin is administered via subcutaneous injection. Mecasermin is available for three treatment phases (initial treatment phase, continuing treatment phase and non-PBS subsidised to PBS-subsidised supply treatment phase). The listing of mecasermin will address a high and urgent unmet clinical need, as there are no other reimbursed or Therapeutic Goods Administration (TGA) registered options for this patient population.

**Paediatric Listing of Somatrogon**

The Pharmaceutical benefits Advisory Committee (PBAC) recommended the listing of somatrogon for the treatment of paediatric patients with:

* short stature associated with biochemical growth hormone deficiency (SSABGHD); or
* short stature and slow growth (SSSG).

The PBS restrictions for somatrogon are consistent with the current restrictions for the somatropin brand Genotropin ® (currently five treatment phases) where the stated PBS indication is in common, however it includes two new treatment phases:

* changing drug treatment phase; and
* non‑PBS-subsidised to PBS-subsidised supply treatment phase.

The *changing drug treatment phase* applies to somatrogon or somatropin. It allows for a child to move from somatropin to somatrogon and somatrogon to somatropin. Allowing a child to move from somatropin to somatrogon means that instead of having daily injections (somatropin) they can have weekly injections (somatrogon).

The *non-PBS-subsidised to PBS-subsidised supply treatment phase* applies to somatrogon.

**Online PBS Authorities System for Growth Hormone Prescriptions**

Prescribers can lodge authority applications and receive ‘real-time’ responses via the Online PBS Authorities (OPA) system for all growth hormone prescriptions. Further information on obtaining authority approval via the OPA system is available on the [Services Australia website](https://www.servicesaustralia.gov.au/request-authority-using-online-pbs-authorities-hpos?context=22866). The forms and strengths, brands and restriction criteria for the PBS supply of [mecasermin](https://www.pbs.gov.au/pbs/search?term=mecasermin) and [somatrogon](https://www.pbs.gov.au/pbs/search?term=somatrogon) are available on the PBS website.

## Active Ingredient Prescribing for Computer-Generated Growth Hormone Prescriptions

## The inclusion of the active ingredient on all eligible computer-generated PBS prescriptions became mandatory from 1 February 2021. This means that for paediatric growth hormone prescriptions that are computer-generated, prescribers must specify on the Authority prescription the active ingredient name (i.e. somatrogon or mecasermin) as well as the brand and form and strength of growth hormone being prescribed to the patient.

## 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 is defined as a person who:

* is 18 years of age or older and has late onset growth hormone deficiency; or
* has a mature skeleton; or
* has a diagnosis of Prader-Willi Syndrome and is aged 18 years or older.

A child is defined as a person who:

* is not an adult; or
* has a diagnosis of Prader-Willi Syndrome and is less than 18 years of age.

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.

## Who is eligible to prescribe growth hormone mecasermin?

For:

* initial treatment in **children**, mecasermin pharmaceutical benefits must be prescribed by a paediatric endocrinologist or a paediatrician who has consulted a paediatric endocrinologist;
* continuing treatment in **children**, mecasermin pharmaceutical benefits must be prescribed by a paediatric endocrinologist or a paediatrician who has consulted a paediatric endocrinologist;
* for non‑PBS to PBS‑subsidised supply in children, mecasermin pharmaceutical benefits must be prescribed a paediatric endocrinologist or a paediatrician who has consulted a paediatric endocrinologist. For this treatment phase, the patient must have commenced non‑PBS‑subsidised treatment with this drug prior to 1 October 2022.

## Who is eligible to prescribe growth hormone somatrogon?

For treatment in **paediatrics** for eithershort stature associated with biochemical growth hormone deficiency (SSABGHD) or short stature and slow growth (SSSG), somatrogon 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 for initial and change of drug treatment phases; and
* a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or
* a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics for recommencement, recommencement as a reclassified patient, continuing, continuing treatment as a reclassified patient and from non‑PBS to PBS‑subsidised supply (‘Grandfather’ arrangements) treatment phases.

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

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

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

The PBS listing of somatrogon for **paediatric** patients includes provisions to grandfather patients who have previously received non-PBS-subsidised treatment with somatrogon 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](https://www.servicesaustralia.gov.au/health-professionals-forms-title).

Applications for authority to prescribe growth hormone can also be made in real time using the [Online PBS Authorities](https://www.servicesaustralia.gov.au/request-authority-using-online-pbs-authorities-hpos?context=22866) system. For more information visit one of the following Services Australia webpages:

* [Growth hormone deficiency – paediatric patients](https://www.servicesaustralia.gov.au/growth-hormone-deficiency-paediatric-patients?context=23021);
* [Growth hormone deficiency – childhood onset or late onset](https://www.servicesaustralia.gov.au/growth-hormone-deficiency-childhood-onset-or-adult-onset?context=23021); or
* [Severe growth failure with primary insulin-like growth factor-1 deficiency](https://www.servicesaustralia.gov.au/severe-growth-failure-with-primary-insulin-like-growth-factor-1-deficiency?context=23021)

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 two 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](https://www.servicesaustralia.gov.au/request-authority-using-online-pbs-authorities-hpos?context=22866) system, the assessment is made and returned in real time. Online authority applications can be submitted 24 hours a day, seven 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 may submit written applications in [Health Professional Online Services](https://www.servicesaustralia.gov.au/form-upload-hpos?context=22786) (HPOS) using the form upload function or by post. 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 two 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 (a mandatory element for inclusion on all eligible computer-generated PBS prescriptions from 1 February 2021) 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 vials or pens required?

The prescriber is responsible for calculating each patient’s weekly dose of growth hormone and the number of vials or pens 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 SOMATROGON ONLY recommended for use is available on the [PBS website](https://www.pbs.gov.au/info/browse/section100-gh).

## 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).