Pharmaceutical Benefits Scheme (PBS) section 100 Growth Hormone Program (mecasermin, somapacitan and somatrogon)

July 2026

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.

Paediatric listing of mecasermin

Mecasermin is listed on the PBS for the long-term treatment of growth failure in children and adolescents from 2 years to 17 years (inclusive) 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 2 treatment phases (initial treatment phase and continuing treatment phase).

Paediatric listings of somapacitan and somatrogon

Somapacitan and somatrogon are listed on the PBS for the treatment of paediatric patients with:

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

The PBS restrictions for somapacitan and somatrogon are consistent with the current restrictions for the somatropin brand Genotropin® (currently 6 treatment phases) where the stated PBS indication is in common, with the inclusion of one additional treatment phase for "grandfathered" patients transitioning from non-PBS to PBS-subsidised treatment (the non-PBS to PBS-subsidised supply treatment phase).

The change of drug treatment phase applies to somapacitan, somatrogon and somatropin. It allows for an eligible child to transition from any PBS-subsidised growth hormone to any other where prescribed for the same indication (i.e. from somapacitan to somatrogon or somatropin; from somatrogon to somapacitan or somatropin; or from somatropin to somapacitan or somatrogon). Allowing an eligible child to move from somatropin to somapacitan or somatrogon means that instead of having daily injections (somatropin), they can have weekly injections (somapacitan or somatrogon).

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

A child is defined as a person who:

- has a non-mature skeleton; or
- has 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 growth hormone are available on the PBS website.

Who is eligible to prescribe 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

Who is eligible to prescribe somapacitan and somatrogon?

For paediatric treatment for either SSABGHD or SSSG, somapacitan and somatrogon pharmaceutical benefits can be prescribed by:

- a specialist or consultant physician in paediatric endocrinology (all treatment phases); or
- a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology (all treatment phases); or
- a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology or general paediatrics (recommencement, recommencement as a reclassified patient, continuing as a reclassified patient and non-PBS to PBS-subsidised supply (“grandfather” arrangements) treatment phases only); or
- a medical practitioner (continuing treatment phase only).

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

The PBS listings of somapacitan and somatrogon for paediatric patients include provisions to "grandfather" patients who have previously received non-PBS-subsidised treatment with somapacitan or somatrogon as a child (i.e. transition them to receiving PBS-subsidised paediatric treatment with the respective growth hormone). 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?

Applications for authority to prescribe growth hormone can 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
- Growth hormone deficiency – childhood onset or late onset or
- Severe growth failure with primary insulin-like growth factor-1 deficiency.

Written Authority application forms for authority to prescribe growth hormone are available on the Services Australia website.

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.

Prescribers may submit written applications in Health Professional Online Services (HPOS) using the form upload function or by post. Prescribers submitting authority applications by post will need to factor in the time required for the application to be received by Services Australia and the time it will take for the authority approval details to be communicated to the prescriber.

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, 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 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.

The forms and strengths, brands and restriction criteria for the PBS supply of mecasermin, somapacitan and somatrogon are available on the PBS website.

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 somatrogon prescribed maximum quantity by weight is available on the PBS website.

Guidance in relation to prescribing an appropriate amount of somapacitan for various patient weight ranges (in terms of the maximum quantity in units required for the relevant treatment period based on the different strength presentations of this drug) is outlined in the Administrative Advice accompanying the PBS restrictions for somapacitan (see 'Note' attached to the relevant listing on the PBS website).

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 Reform Agreements (PRAs) (i.e., PRAs are not in place between the Commonwealth and these jurisdictions).