



Overview of recent changes

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

On 1 January 2020, the **adult** listing of somatropin was amended to improve clarity and access for patients with childhood onset growth hormone deficiency (CO-GHD) due to congenital, genetic or structural cause. These changes allow patients with CO-GHD due to a congenital, genetic or structural cause to be eligible for adult use somatropin, if they meet the 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 the age of 18 years. Patients with Prader-Willi syndrome, are eligible for adult use somatropin at the age of 18 years or over.

Additionally, CO-GHD patients due to a congenital, genetic or structural cause who have previously received PBS-subsidised therapy as children are no longer required to provide provocation tests to meet the eligibility criteria for adult use somatropin.

Somatropin is also listed on the PBS for use in **paediatric** patients with a variety of growth hormone deficiency indications. In February 2019, the eligibility criteria was broadened for improved access to PBS-subsidised growth hormone for paediatric patients in special clinical circumstances.

The Department is working towards prescribers being able to lodge Authority applications and receive 'real time' responses via the Online PBS Authorities System for all growth hormone prescriptions. This will be similar to the current paediatric growth hormone online Authority application system. Further information will be provided to prescribers once the online system becomes available.

The forms, brands and restriction criteria for the supply of somatropin under the PBS as a pharmaceutical benefit are available at www.pbs.gov.au.

GROWTH HORMONE PROGRAM

Do the 1 January 2020 changes affect access to growth hormone for paediatric use?

No. The amendments to adult use growth hormone do not change the existing listing of and access to growth hormone for children. Patient criteria and prescriber eligibility for paediatric growth hormone remain unchanged.

On 1 February 2019, the eligibility criteria was broadened for improved access to PBS-subsidised growth hormone for paediatric patients in special clinical circumstances. A Quick Reference Guide for Prescribers is available at www.pbs.gov.au/info/general/changes-to-certain-s100-programs.

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 an adult and a child.

An adult is defined as being a person who:

- a) is 18 years of age or older and has adult onset growth hormone deficiency; or
- b) has a mature skeleton; or
- c) has a diagnosis of Prader-Willi syndrome and is aged 18 years or older

A child means a person who:

- d) is not an adult; or
- e) has a diagnosis of Prader-Willi syndrome and is less than 18 years of age.

Prescribers should ensure the appropriate restrictions are met at the time of prescribing.

Who is eligible to prescribe growth hormone?

For initial treatment in **adults**, the pharmaceutical benefit (somatropin) must be prescribed by an endocrinologist. For continuing treatment, the pharmaceutical benefit must be prescribed by an endocrinologist or in consultation with an endocrinologist.

For treatment in **children**, the pharmaceutical benefit 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.

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

The restriction criteria outlines the testing requirements necessary to support an authority application.

Provocation tests include:

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

CO-GHD patients due to a congenital, genetic or structural cause who have previously received PBS-subsidised therapy as children are no longer required to provide provocation tests to meet the eligibility criteria for adult use somatropin as evidence of growth hormone deficiency was provided in childhood.

GROWTH HORMONE PROGRAM

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

The **adult** listing includes provisions to grandfather patients who have previously received non PBS- subsidised treatment with somatropin prior to 1 December 2018. Patients in this category must demonstrate that they met all the initial restriction criteria prior to initiating their non PBS-subsidised treatment. A grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a grandfathered patient must qualify under the criteria for continuing treatment.

How do I submit an Authority application?

Written authority application forms are available from Department of Human Services (DHS) website at www.humanservices.gov.au/organisations/health-professionals/forms.

Certain growth hormone applications are available using the [Online PBS Authorities system](#). For more information about which authority applications are available online visit the DHS [growth hormone program](#) page or via www.humanservices.gov.au.

Any queries regarding prescribing arrangements may be directed to DHS on 1800 700 270 (hours of operation: 8am to 5pm EST, 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 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 applications made online, the assessment is in real time. Online Authority applications can be submitted 24/7.

For written applications, DHS will generally process applications in order of receipt and they will be completed as soon as possible. As an estimate, please allow at least two weeks for DHS 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 DHS via post 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 the pharmacy, time will be required for the pharmacy to order the growth hormone supply 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 DHS 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 somatropin prescriptions, the prescriber MUST specify on the Authority prescription the form, strength and brand of growth hormone being prescribed to the patient.

The same brand (including the 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 DHS.

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

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

The Paediatric Dose and Cartridge Quantity Calculator recommended for use is available at 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 need to contact DHS 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.

How will the changes impact pharmacists?

From 1 January 2020, pharmacies may see additional growth hormone PBS Written Authority prescriptions being presented for dispensing for the treatment of adults with growth hormone deficiencies.

Note that prescriptions written for public patients of NSW and ACT public hospital clinics cannot be dispensed under the PBS, as these jurisdictions do not participate in the Pharmaceutical Reforms.

What do the changes mean for patients?

From 1 January 2020, adult patients with CO-GHD due to a congenital, genetic or structural cause are able to access PBS-subsidised growth hormone through community, private or public hospital pharmacies if they meet the PBS restriction criteria. The usual PBS co-payment will apply for each dispensing of growth hormone.

These changes allow patients with CO-GHD due to a congenital, genetic or structural cause to be eligible for adult use somatropin, if they meet the 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 now eligible to access growth hormone as adults once skeletal maturity is reached, rather than waiting until they reach the age of 18 years. Patients with Prader-Willi syndrome are eligible for adult use somatropin at the age of 18 year or over.

Additionally, CO-GHD patients due to a congenital, genetic or structural cause who have previously received PBS-subsidised therapy as children are no longer required to provide provocation or stimulation tests to meet the eligibility criteria for adult use somatropin.