# SOMATROPIN

| | |
|---|---|
| Source | S100 Growth Hormone Programme |
| Body System | SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS > PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES > ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES |

Note

Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs Programs

Reply Paid 9826

HOBART TAS 7001

**Note**

No increase in the maximum number of repeats may be authorised.

Authority Required

Severe growth hormone deficiency

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by an endocrinologist.

**Clinical criteria:**

- Patient must have a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause; OR
- Patient must have adult onset growth hormone deficiency secondary to organic hypothalamic or pituitary disease,

**AND**

- Patient must have an insulin tolerance test with maximum serum growth hormone (GH) less than 2.5 micrograms per litre; OR
- Patient must have an arginine infusion test with maximum serum GH less than 0.4 micrograms per litre; OR

- Patient must have a glucagon provocation test with maximum serum GH less than 3 micrograms per litre,

**AND**

- Patient must have a quality of life (QoL) score on the Quality of Life Assessment of Growth Hormone Deficiency in Adults (QoL-AGHDA) instrument of 16 or greater.

**Population criteria:**

- Patient must be aged 18 years or older.

Grandfathered patient who has previously received non-PBS subsidised treatment with this drug for this condition prior to 1 December 2018 must have met all the initial restriction criteria prior to initiating non-PBS subsidised treatment. Additional information of a baseline serum IGF-1 measurement, including the date of testing and laboratory reference range for age and sex, of less than 12 weeks prior to initiating non-PBS subsidised treatment with this drug for this condition; and QoL score on the QoL-AGHDA instrument of 16 or greater, of less than 12 weeks prior to initiating non-PBS-subsidised treatment with this drug for this condition must be provided at the time of application. 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 Continuing treatment criteria.

The authority application must be in writing and must include:

- A completed authority prescription form; AND
- A completed Severe Growth Hormone Deficiency supporting information form; AND
- Confirmation of childhood onset growth hormone deficiency due to a congenital, genetic or structural cause; OR
- Confirmation of adult onset growth hormone deficiency due to organic hypothalamic or pituitary disease; AND
- Results of the growth hormone stimulation testing, including the date of testing, the type of test performed, the peak growth hormone concentration, and laboratory reference range for age/gender; AND
- A baseline serum IGF-1 measurement, including the date of testing and laboratory reference range for age and sex, of less than 12 weeks old at the time of application; AND
- The patient's QoL score on the QoL-AGHDA instrument, including the date of testing, of less than 12 weeks old at the time of application.

Authority Required
Severe growth hormone deficiency

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by an endocrinologist or in consultation with an endocrinologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy with this drug for this condition at the age of 18 years or older,

**AND**

- Patient must maintain IGF-1 levels within the normal range for age and sex,

**AND**

- Patient must maintain a quality of life (QoL) score on the Quality of Life Assessment of Growth Hormone Deficiency in Adults (QoL-AGHDA) instrument with a reduction of more than 7 points from baseline.

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be in writing and must include:

- A completed authority prescription form; AND
- A completed Severe Growth Hormone Deficiency supporting information form; AND
- A serum IGF-1 measurement, including the date of testing and laboratory reference range for age and sex, of less than 12 weeks old at the time of application; AND
- The patient's QoL score on the QoL-AGHDA instrument, including the date of testing, of less than 12 weeks old at the time of application.