

12 March 2010

Funding of somatropin treatment for growth hormone deficient adults and adolescents will commence on 1 April 2010

PHARMAC is pleased to announce the implementation, from 1 April 2010, of widened access to subsidised somatropin (growth hormone) to include growth hormone deficient adults and adolescents. The decision to widen access was the subject of a notification letter dated 7 December 2009¹. In summary:

- Subsidised access to somatropin will become available to growth hormone deficient adults and adolescents who meet Special Authority criteria, from 1 April 2010;
- A Panel has been established to consider whether individuals are eligible for subsidised treatment under the Special Authority criteria; and
- The price and subsidy of the Genotropin brand of somatropin (listed under Sole Subsidised Supply until 31 December 2013) will be reduced from 1 April 2010.

Details of the proposal

Widened Access

PHARMAC will be widening access to funded somatropin for adults and adolescents who are growth hormone deficient and who meet the Special Authority criteria for somatropin funding.

PHARMAC has also established an Adult Growth Hormone Panel to review applications and determine eligibility for funded access from 1 April 2010. All members of the Adult Growth Hormone Panel are also members of the Growth Hormone Subcommittee of PTAC. This access mechanism is similar to the current Panel that considers growth hormone applications relating to paediatric patients.

The Special Authority criteria for adult and adolescent patients with growth hormone deficiency are as follows:

ENTRY AND EXIT CRITERIA FOR SOMATROPIN FUNDING

Applications for growth hormone therapy in growth hormone deficient adults and adolescents are assessed by the Adult Growth Hormone Panel. In view of the complexity of growth hormone deficiency in adults and adolescents, each individual application is thoroughly evaluated to determine the appropriateness of growth hormone therapy. Applications for treatment and any queries regarding the criteria should be directed to PHARMAC.

Initial applications are valid for a period of nine months after which time a renewal application should be submitted to the Adult Growth Hormone Panel for assessment of eligibility for ongoing funding. Renewal applications are then required on an annual basis.

¹ <http://www.pharmac.govt.nz/2009/12/07/2009-12-07%20Somatropin%20Sole%20supply.pdf>

Entry Criteria (all of the following):

- The presence of a medical condition known to cause growth hormone deficiency (e.g. surgical removal of the pituitary for treatment of a pituitary tumour).
- Appropriate treatment of other hormonal deficiencies and psychological illnesses.
- Severe growth hormone deficiency defined as a peak serum GH level $\leq 3\mu\text{g/l}$ (9mU/l) during an adequately performed insulin tolerance test or cross-validated equivalent test. In patients with multiple pituitary deficiencies one test would be sufficient. In patients with no other anterior pituitary deficiency two growth hormone stimulated tests should be performed.
- Serum IGF-1 more than 1 SD below the mean for age and sex.
- Poor quality of life as defined by a score of ≥ 16 using the disease-specific quality of life questionnaire for adult growth hormone deficiency (QoL-AGHDA).

Exit Criteria (any of the following):

- Major adverse effects of treatment.
- Patient preference not to continue treatment.
- Failure to reach or maintain serum IGF-I levels within 1SD of the mean normal value for age and sex despite use of ceiling doses of growth hormone (0.7mg/day in males, 1mg/day in females).
- Failure to improve > 7 points on the QoL-AGHDA score from baseline.
- Once stable on growth hormone treatment, a deterioration in the QoL-AGHDA score by > 5 points unrelated to obvious external factors on 2 measurements > 6 months apart.
- Unsatisfactory follow-up or compliance.

Price reduction

As a result of access to somatropin being widened to include adult and adolescent patients who are growth hormone deficient, the price and subsidy of Genotropin will reduce from 1 April 2010, as outlined below (prices and subsidies are ex-manufacturer, excluding GST):

Chemical	Presentation*	Brand	Pack size	Price and subsidy from 1 January 2010	Price and subsidy from 1 April 2010
somatropin	Inj 36 IU (12 mg)	Genotropin	1	\$561.60	\$360.00
somatropin	Inj 16 IU (5.3 mg)	Genotropin	1	\$249.60	\$160.00

* Note the presentation has been amended to also include the total amount of somatropin in mg.

Feedback received

PHARMAC consulted on a proposal to award Pfizer New Zealand Limited Sole Subsidised Supply of somatropin in October 2009. This consultation also outlined the proposal to widen subsidised access to somatropin to include growth hormone deficient adults and adolescents. During consultation, no issues were raised regarding the proposed criteria for this patient group or the proposed access mechanism. On 7 December 2009, PHARMAC notified that a decision had been made to proceed with the proposal, with the implementation date of widened access to be finalised once a Panel had been established.

More information

Application forms will be available from the Special Authority form page of PHARMAC's website from 19 March 2010: <http://www.pharmac.govt.nz/healthpros/Schedule/SAForms>.

If you have any questions about this decision, you can call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50 or email growthhormone@pharmac.govt.nz.