

7 December 2009

## Approval of sole supply arrangement for the biologic treatment, somatropin (growth hormone)

PHARMAC is pleased to announce the approval of an agreement with Pfizer New Zealand Limited in relation to somatropin. This was the subject of a consultation letter dated 29 October 2009. In summary, the effect of the decision is that:

- Genotropin will be the only subsidised brand of somatropin from 1 July 2010 to 31 December 2013.
- The price and subsidy of Genotropin will be reduced from 1 January 2010.
- Subsidised access to somatropin will be widened to include adult and adolescent patients with growth hormone deficiency who meet certain access criteria. The date of access widening is yet to be determined, but will occur after 1 January 2010 and prior to 1 July 2010, following establishment of a Panel to determine eligibility.

### Details of the proposal

#### *Genotropin sole subsidised supply*

Genotropin will be the only subsidised brand of somatropin in Section B of the Pharmaceutical Schedule from 1 July 2010. From the 1 July 2010 the Nordotropin SimpleXx brand of somatropin (supplied by Novo Nordisk) will be delisted from the Pharmaceutical Schedule and Genotropin will be the only subsidised brand.

A six month transition period will commence on 1 January 2010. During this transition period Pfizer will work with clinicians to assist in switching patients from Norditropin SimpleXx to Genotropin.

#### *Price reductions*

The price and subsidy of Genotropin will reduce from 1 January 2010, with a further reduction upon access to somatropin being widened to include adult and adolescent patients who are growth hormone deficient, 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 upon widened access
Somatropin	Inj 16 IU	Genotropin	5	\$1,248.00	\$800.00
Somatropin	Inj 36 IU	Genotropin	5	\$2,808.00	\$1,800.00

## **Widened Access**

PHARMAC will be widening funded access to growth hormone for adults and adolescents who are growth hormone deficient and will be establishing an Adult Growth Hormone Panel to review applications and determine eligibility for funded access. The entry and exit criteria for adult and adolescent patients with growth hormone deficiency are as follows:

### *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  $\geq 16$  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.

The date of implementation for widening of access will be dependant on the establishment of the Adult Growth Hormone Panel, but is anticipated to occur between 1 January 2010 and 30 June 2010. The Adult Growth Hormone Panel will run in a similar way to the current paediatric Growth Hormone Panel, where applications for funding will be reviewed and determined by the panel.

## Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 12 November 2009 were considered in their entirety in making a decision on the proposed changes. The following issues were raised in relation to specific aspects of the proposal:

Theme	Comment
The current distribution model is direct distribution from one pharmacy to patients, is this distribution model likely to change?	We have not amended the current distribution model for somatropin.  We note that there is a discussion document regarding distribution of certain pharmaceuticals currently inviting feedback.
There is the potential for some patients to have an allergy to medications and the option for this should be provided.	There is always the potential for patients to have an allergy to any medication when Sole Supply is initiated. True allergies can be dealt with on a case by case basis.
A liquid preparation would be preferable as the mixing of powder with diluent confuses some patients.	We consulted with the New Zealand Growth Hormone Committee regarding the suitability of the device and the Committee considered that the Pfizer product was acceptable, although they noted that a liquid preparation would be preferable.  We also note that 50% of patients receiving somatropin currently use the Pfizer brand and we are unaware of any patient switching brands due to reconstitution issues.

## More information

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.