

24 February 2010

Proposal to Amend Growth Hormone Access Criteria

PHARMAC is seeking feedback on a proposal to make several amendments to the Growth Hormone Access Criteria.

In summary, this proposal would result in:

- a revision of the cut-off levels, due to changes in measurement technology, for partial and complete growth hormone deficiency from 7.0 µg/L and 4.0 µg/L to 5.0 µg/L and 3.0 µg/L respectively, and
- the incorporation of several guidelines in the Prader-Willi Syndrome Entry Criteria.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Friday, 12 March 2010** to:

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All feedback received before the closing date will be considered by PHARMAC's Board (or Chief Executive acting under delegated authority) prior to making a decision on this proposal.

Details of the proposal

Over time, growth hormone assays have progressively improved through the use of more specific antibodies, resulting in the gradual fall of reported growth hormone values. A new assay standard was recently adopted that further reduced the reported growth hormone values, triggering a review of growth hormone assays across New Zealand in late 2009.

As a result of this review, the cut-off levels used to diagnose growth hormone deficiency have been revised significantly by the New Zealand Growth Hormone Committee. The previous values of < 7.0 µg/L for partial growth hormone deficiency and < 4.0 µg/L for complete growth hormone deficiency have been revised to < 5.0 µg/L and < 3.0 µg/L respectively.

As a result of these changes the Growth Hormone Access Criteria now need to be reconsidered with a view to ensuring that funded growth hormone access remains targeted to the same group of patients as previously.

The following guidelines would be added to the Entry Criteria for children with Prader-Willi Syndrome:

Patients approved for treatment with growth hormone should undergo a DXA scan prior to starting treatment and on an annual basis during treatment to better analyse the effects of growth hormone and therefore to provide evidence of its efficacy.

Careful consideration should be given in cases of severe obesity (defined as greater than 3 Standard Deviation Scores (SDS) above the mean) with rapid weight gain (greater than 0.5 SDS in 6 months). In this situation any obesity related complications should be well managed prior to initiation of therapy.

IGF-1 levels should be monitored to ensure the dose of growth hormone is not too high and, if IGF-1 levels are more than two standard deviations above the mean, the dose should be titrated down to bring IGF-1 levels closer to the normal range.

We note that these are guidelines only and are not entry criteria that must be adhered to. They are useful in guiding the appropriate management of patients prior to commencing and during treatment with growth hormone.

Background

In January 2010, the New Zealand Growth Hormone Committee notified PHARMAC staff of changes to growth hormone deficiency cut-off levels that had resulted from the incorporation of a new growth hormone assay standard. The changes outlined in this proposal are in response to the changes resulting from the incorporation of this new standard.

The update to the Prader-Willi Syndrome criteria would reflect guidelines that were recommended by the Growth Hormone Subcommittee of PTAC in October 2007 but were inadvertently left out when the criteria were updated in March 2009.