Issue date: **August 2003**
Review date: **July 2006**

NHS

National Institute for Clinical Excellence

Human growth hormone (somatropin) in adults with growth hormone deficiency

1 Guidance

1.1 Recombinant human growth hormone (somatropin) treatment is recommended for the treatment of adults with growth hormone (GH) deficiency only if they fulfil all three of the following criteria.

- They have severe GH deficiency, defined as a peak GH response of less than 9 mU/litre (3 ng/ml) during an insulin tolerance test or a cross-validated GH threshold in an equivalent test.
- They have a perceived impairment of quality of life (QoL), as demonstrated by a reported score of at least 11 in the disease-specific 'Quality of life assessment of growth hormone deficiency in adults' (QoL-AGHDA) questionnaire.
- They are already receiving treatment for any other pituitary hormone deficiencies as required.

1.2 The QoL status of people who are given GH treatment should be re-assessed 9 months after the initiation of therapy (an initial 3-month period of GH dose titration, followed by a 6-month therapeutic trial period). GH treatment should be discontinued for those people who demonstrate a QoL improvement of less than 7 points in QoL-AGHDA score.

1.3 Patients who develop GH deficiency in early adulthood, after linear growth is completed but before the age of 25 years, should be given GH treatment until adult peak bone mass has been achieved, provided they satisfy the biochemical criteria for severe GH deficiency (defined as a peak GH response of less than 9 mU/litre (3 ng/ml) during an insulin tolerance test or a cross-validated GH threshold in an equivalent test). After adult peak bone mass has been achieved, the decision to continue GH treatment should be based on all the criteria in Section 1.1.

Technology Appraisal Guidance 64

1.4 Patients currently receiving GH treatment, for the management of adult onset GH deficiency, whether as routine therapy or as part of a clinical trial, could suffer loss of well being if their treatment were to be discontinued at a time they did not anticipate. Because of this, all NHS patients who are on therapy at the date of publication of this guidance should have the option to continue treatment until they and their consultant consider it is appropriate to stop.

1.5 Children with GH deficiency should be treated as outlined in the Institute's guidance on the use of GH in children (*NICE Technology Appraisal Guidance* No. 42). At completion of linear growth (that is, growth rate < 2 cm/year), GH treatment should be stopped for 2–3 months, and then GH status should be re-assessed. GH treatment at adult doses should be re-started only in those satisfying the biochemical criteria for severe GH deficiency (defined as a peak GH response of less than 9 mU/litre (3 ng/ml) during an insulin tolerance test or a cross-validated GH threshold in an equivalent test), and continued until adult peak bone mass has been achieved (normally around 25 years of age). After adult peak bone mass has been achieved, the decision to continue GH treatment should be based on all the criteria set out in Section 1.1.

1.6 Initiation of GH treatment, dose titration and assessment of response during trial periods should be undertaken by a consultant endocrinologist with a special interest in the management of GH disorders. Thereafter, if maintenance treatment is to be prescribed in primary care, it is recommended that this should be under an agreed shared-care protocol.

Ordering information
Copies of this summary can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting ref: N0266. For copies of the full guidance quote reference number N0265. Information for the public can be obtained by quoting reference number N0267 for the English version and N0268 for a version in English and Welsh.

Published by the National Institute for Clinical Excellence, August 2003 ISBN: 1-84257-356-8

National Institute for Clinical Excellence
MidCity Place, 71 High Holborn, London WC1V 6NA, web: www.nice.org.uk