

## **PRESS RELEASE**

### **Latest NICE guidance sets out recommendations on clinical and cost effectiveness of growth hormone for adults**

The National Institute for Clinical Excellence (NICE) has issued guidance on the use of human growth hormone (GH) for adults with growth hormone deficiency within the NHS in England and Wales.

Today's publication provides guidance for three groups: those developing growth hormone deficiency as adults (over 25 years); those who develop growth hormone deficiency in early adulthood (under 25 years); and the transition from childhood to adult treatment.

NICE has recommended that human growth hormone should be used only for adults with severe growth hormone deficiency that is significantly affecting their quality of life. To be a part of this group, NICE says a person should:

- have a peak growth hormone response of less than 9 mU/litre in the 'insulin tolerance test' for growth hormone deficiency or a similar low result in another reliable test, **and**
- have an impaired quality of life because of their growth hormone deficiency (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), **and**
- already be receiving replacement hormone treatment for any other deficiencies of pituitary hormones if he or she has one or more other deficiencies.

NICE has also said that people who have recombinant human growth hormone should have their quality of life checked again 9 months after starting the treatment. This is so that treatment can be stopped if it isn't having a positive effect, which is

judged to be the case if the person's score on the quality of life questionnaire hasn't improved by at least 7 points.

### ***Diagnosis in early adulthood***

For people who develop growth hormone deficiency in early adulthood (before 25 years of age), after their growth has slowed down (that is they grow less than 2 cm in a year) NICE has recommended that the level of growth hormone should be checked. If the peak growth hormone response is less than 9 mU/litre in the insulin tolerance test for growth hormone deficiency or there is a similar low result in another reliable test, then growth hormone treatment should be given until what is known as 'adult peak bone mass' is achieved (this happens at around age 25 years). After adult peak bone mass has been achieved an assessment of whether it is appropriate to continue with the human growth hormone treatment should be made, in line with the three measures described in the bullet points above for adults.

Someone receiving NHS treatment with recombinant human growth hormone before the NICE guidance was issued should have the option of continuing treatment until he or she and the consultant responsible for their treatment consider it appropriate to stop.

### ***Transition from childhood to adult treatment***

NICE has previously issued guidance on the use of human growth hormone in children (<http://www.nice.org.uk/cat.asp?c=32239>). In today's guidance on the use of growth hormone in adults, NICE has made the following recommendation for people who have been receiving treatment for childhood growth hormone deficiency:

- When a person's growth has slowed down (that is, when he or she grows less than 2 cm in a year), the growth hormone treatment should be stopped for 2 or 3 months.
- The person's level of growth hormone should then be re-checked. If the person has a peak growth hormone response of less than 9 mU/litre in the insulin tolerance test for growth hormone deficiency or a similar low result in another reliable test, NICE recommends that human growth hormone treatment should be restarted and continued until adult peak bone mass is achieved. At this time, an

assessment of whether it is appropriate to continue with the human growth hormone treatment can be made, in line with the three measures described at the beginning of this section (listed as bullet points).

**Anne-Toni Rodgers, Corporate Affairs Director and Executive Lead said:** “We were asked to look at this treatment because of genuine uncertainty as to its long term value for patients had resulted in so called ‘post code prescribing’. The process NICE follows is genuinely consultative and involves bringing all of the evidence together and engaging with professionals and patients. Today’s guidance provides clear advice to the NHS and patients, no matter where they live in England and Wales, on where this treatment can add value.”

**Professor David Barnett, Chair of the Appraisal Committee said:** “The Committee considered in detail the effect of growth hormone replacement on overall mortality from various causes in people with growth hormone deficiency, and we concluded that it is uncertain what impact growth hormone treatment has on the longer-term clinical outcomes and mortality related to cardiovascular risk factors and changes in bone mineral density. However we were persuaded that there was a subgroup of people with growth hormone deficiency for whom the deficiency significantly impaired their quality of life and for whom the benefits of growth hormone replacement could be both clinically and cost effective.”

**Professor Barnett added,** “Further good-quality studies are needed in this area to investigate the relationship between mortality rates and growth hormone deficiency and to look at the effectiveness of treatment in different populations.”

**Ends**

## **Notes to Editors**

### **About growth hormone deficiency**

1. In most people, growth hormone is produced by the pituitary gland, which lies at the base of the brain. Naturally occurring human growth hormone is also called somatotrophin. It helps to control the body’s use of proteins, carbohydrates and lipids (fats and fat-like substances). Growth hormone is also involved in the growing process in children, as it has an effect on the growth of bones.
2. Growth hormone deficiency is the term used when the amount of growth hormone produced is much lower than usual. In adults, growth hormone deficiency can happen as the result of damage to the pituitary gland or to the part of the brain called the hypothalamus, which is closely linked to the pituitary. Such damage can be caused by a tumour in the area or by the treatment the person had for a tumour (surgery or

radiotherapy). Growth hormone deficiency can also happen if there has been a problem with the blood supply to the pituitary and hypothalamus.

3. It is possible to replace the missing growth hormone by having regular injections of human growth hormone. The NICE appraisal looked at the synthetic version of human growth hormone (somatropin); this is sometimes referred to as 'recombinant growth hormone', which means that it's manufactured using DNA technology.

#### **About the NICE guidance**

4. NICE follows a process which allows consultees, including patients and health professionals to submit evidence, nominate their own experts, be consulted on draft guidance and appeal if they feel the guidance is perverse, that NICE has exceeded its powers or if NICE has not followed the published process for its work. An appeal panel was convened on 3 July 2003 to consider appeals for this appraisal. The appeal panel dismissed the appeal on all grounds, however it did recommend some wording changes to the final appraisal determination. The decision of the appeal panel is available from the NICE web site (<http://www.nice.org.uk/cat.asp?c=83406>).

#### **About NICE**

5. NICE is part of the NHS. It is the independent organisation responsible for providing national guidance on treatments and care for those using the NHS in England and Wales. Its guidance is for healthcare professionals and patients and their carers to help them make decisions about treatment and healthcare. For further information about NICE you can visit [www.nice.org.uk](http://www.nice.org.uk).
6. NICE produces guidance in three areas of health:
  - the use of new and existing medicines and treatments within the NHS in England and Wales – technology appraisals
  - the appropriate treatment and care of patients with specific diseases and conditions within the NHS in England and Wales – clinical guidelines.
  - whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for routine use– interventional procedures.
7. NICE also funds three enquiries that undertake research into the way patients are treated to identify ways of improving the quality of care (the investigations are known as confidential enquiries).
8. NICE guidance and recommendations are prepared by independent groups that include professionals working in the NHS and people who are familiar with the issues affecting patients and carers.