

The use of human growth hormone (somatropin) for adults with growth hormone deficiency

Understanding NICE guidance –
information for people with
growth hormone deficiency,
and the public

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To order copies

Copies of this booklet can be ordered from the NHS Response Line; telephone 0870 1555 455 and quote reference number N0268. A version in English only is also available, quote reference N0267. The NICE technology appraisal on which this information is based, *Guidance on the use of human growth hormone (somatropin) in adults with growth hormone deficiency*, is available from the NICE website (www.nice.org.uk). Copies can also be obtained from the NHS Response Line, reference number N0265.

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What is NICE guidance?

The National Institute for Clinical Excellence (NICE) is part of the NHS. It produces guidance for both the NHS and patients on the use of medicines, medical equipment, diagnostic tests and clinical and surgical procedures. NICE guidance may also cover the circumstances in which a particular item should be used.

To produce the guidance, NICE looks at how well the medicine, equipment or procedure works and also how well it works in relation to how much it costs. This process is called an appraisal. The appraisal process involves the manufacturer of the medicine or equipment for which guidance is being produced, and the organisations that represent the healthcare professionals, patients and carers who will be affected by the guidance.

NICE was asked to look at the evidence available on the use of recombinant (synthetic) human growth hormone (also known as somatropin) for growth hormone deficiency in adults and to produce guidance to help the NHS in England and Wales decide when it should be used.

What is growth hormone deficiency?

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.

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 or hypothalamus.

What is human growth hormone treatment?

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.

What has NICE recommended?

NICE has recommended that recombinant human growth hormone should be used only for adults with severe growth hormone deficiency that is severely 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 (judged using a specific questionnaire called the 'Quality of life assessment of growth hormone deficiency in adults' designed to assess the quality of life in people with growth hormone deficiency; a person should score at least 11 in this 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.

NICE has made the following recommendation for the treatment of 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). 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 at the beginning of this section (listed as bullet points).

Someone who was 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 his or her treatment consider it appropriate to stop.

NICE has already issued guidance on the use of human growth hormone in children. In its guidance on use in adults, NICE has made the following recommendation for people who have been receiving growth hormone treatment for growth hormone deficiency that was identified when they were children. 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).

Finally, NICE has recommended that the first stages of growth hormone treatment (starting treatment, adjusting the dose to suit the person, and assessing how well it's working) should be carried out by a consultant endocrinologist who has a special interest in growth hormone disorders (a consultant endocrinologist is a doctor who has specialised in disorders involving hormones). If, after the first stages, the growth hormone is to be prescribed by the person's GP, then the GP and consultant should 'share' the person's care.

What should I do?

If you or someone you care for has growth hormone deficiency, you should discuss this guidance with your doctor.

Will NICE review its guidance?

Yes. The guidance will be reviewed in June 2006.

Further information

The NICE website (www.nice.org.uk) has further information about NICE and the full guidance on human growth hormone for adults that has been issued to the NHS. The guidance can also be requested from the NHS Response Line by phoning 0870 1555 455 and quoting N0265.

The Institute issued guidance on the use of human growth hormone (somatropin) in children with growth failure in May 2002. Copies are available on the NICE website, or you can request printed copies by phoning the NHS Response Line (quote reference number N0095 for the full guidance; for a version for the families of children with growth failure and the public, quote reference number N0097 for an English version and N0098 for a version in English and Welsh).