NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Final draft guidance

Somatrogon for treating growth disturbance in children and young people aged 3 years and over

1 Recommendations

- 1.1 Somatrogon is recommended, within its marketing authorisation, as an option for treating growth disturbance caused by growth hormone deficiency in children and young people aged 3 years and over.
- 1.2 If people with the condition and their clinicians consider somatrogon to be 1 of a range of suitable treatments (including any preparation of somatropin) discuss the advantages and disadvantages of the available treatments. After that discussion, if more than 1 treatment is suitable, choose the least expensive. Take account of administration costs, dosage, price per dose and commercial arrangements.

Why this decision was made

Growth disturbance caused by growth hormone deficiency is usually treated with somatropin, available in multiple preparations, which are already recommended in NICE's technology appraisal guidance on somatropin. Somatragon works in a similar way, but it is a weekly injection instead of a daily one.

Evidence from clinical trials shows that somatrogon is as effective as one preparation of somatropin (Genotropin).

The cost modelling used a range of dosages of somatropin (0.023 to 0.039 mg/kg per day), which clinical experts advised is the range of doses used in the NHS.

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Using this range of dosages, a cost comparison suggests the costs of somatrogon are similar to those of the somatropin preparations. So somatrogon is recommended.

For all evidence see the <u>external assessment group report and committee papers</u>. To see what NICE did for somatropin, see the committee discussion in NICE's guidance on somatropin.

2 Information about somatrogon

Marketing authorisation indication

2.1 Somatrogon (Ngenla, Pfizer) is indicated for 'the treatment of children and adolescents from 3 years of age with growth disturbance due to insufficient secretion of growth hormone'.

Dosage in the marketing authorisation

2.2 The dosage schedule is available in the <u>summary of product</u> <u>characteristics for somatrogon</u>.

Price

£166.08 per 1.2 ml vial containing 24 mg of somatrogon or £415.20 for a 1.2 ml vial containing 60 mg of somatrogon (excluding VAT, company submission, December 2022). At the recommended dose of 0.66 mg per kg per week the estimated annual cost for a 40 kg patient is £9,500. Costs may vary in different settings because of negotiated procurement discounts.

3 Implementation

3.1 Section 7 of the National Institute for Health and Care Excellence
(Constitution and Functions) and the Health and Social Care Information
Centre (Functions) Regulations 2013 requires integrated care boards,
NHS England and, with respect to their public health functions, local
authorities to comply with the recommendations in this appraisal within
3 months of its date of publication. Because somatrogon has been

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recommended through the cost comparison process, NHS England and integrated care boards have agreed to provide funding to implement this guidance 30 days after publication.

- 3.2 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 2 months of the first publication of the final appraisal document.
- 3.3 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has growth disturbance caused by growth hormone deficiency and the doctor responsible for their care thinks that somatrogon is the right treatment, it should be available for use, in line with NICE's recommendations.

4 Appraisal committee members and NICE project team

Appraisal committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by the <u>chair and vice chair of NICE's highly specialised</u> technologies evaluation committee.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

NICE project team

Each technology appraisal is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the appraisal), a technical adviser and a project manager.

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