NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Consideration of consultation responses on review proposal

Review of TA64; Human growth hormone (somatropin) in adults with growth hormone deficiency

This guidance was issued August 2003.

The review date for this guidance is ‘within 6 months of the publication of trial data according to the last review update in May 2012.

Background

At the GE meeting of 2 September 2014 it was agreed we would consult on the review plans for this guidance. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

Proposal put to consultees:	TA64 should be moved to the static list.
Rationale for selecting this proposal	No new evidence has been found that would justify a review and there is no indication that there are any ongoing studies whose results might change the guidance.

GE is asked to consider the original proposal in the light of the comments received from consultees and commentators, together with any responses from the appraisal team. It is asked to agree on the final course of action for the review.

Recommendation post consultation:	TA64 should be moved to the static list.

Respondent	Response to proposal	Details[1]	Comment from Technology Appraisals
Lilly UK	Agree	We are not aware of any new evidence which would suggest that a review to this appraisal would be beneficial and agree with your proposal to transfer the original guidance to the static list.	Thank you for your comment. No changes to the recommendation are needed.
Sandoz	Agree	We support the proposal to move the existing guidance to the static list.	Thank you for your comment. No changes to the recommendation are needed.
Pituitary Foundation	Agree	We are in agreement with your recommendation to move the existing guidance to the static list and have no further comments.	Thank you for your comment. No changes to the recommendation are needed.
Turner Syndrome Support Society	Agree	We agree with the proposal to move the guidance to the static list.	Thank you for your comment. No changes to the recommendation are needed.

[1] Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Respondent	Response to proposal	Details[1]	Comment from Technology Appraisals
Ferring Pharmaceuticals	Additional evidence for consideration	In regards to this update, Ferring will request NICE to take into consideration the recent publication: http://www.ncbi.nlm.nih.gov/pubmed/25258519 Patient Prefer Adherence. 2014 Sep 17;8:1255-63. Maintaining persistence and adherence with subcutaneous growth-hormone therapy in children: comparing jet-delivery and needle-based devices. Spoudeas HA, Bajaj P, Sommerford N	Thank you for your comment. This study looks specifically at persistence and adherence in children; the use of human growth hormone in children is covered by Technology Appraisal 188. No changes to the recommendation are needed.

Respondent	Response to proposal	Details[1]	Comment from Technology Appraisals
Royal College of Physicians	Agree (with caveat)	Our experts agree with the proposal to move TA64 to the static list, with the guidance staying as it is, for adults. We agree with the summary stating that there is no new significant evidence that would change the guidance. However, we wish to stress that the situation is different for children as there is a recent study where children treated for short stature with GH have increased risk of early adulthood stroke. Our understanding is that a large initiative is underway to try and assess these data and potentially further studies to investigate. We believe that the data are unlikely to be forthcoming ahead of the next 5 year review point planned by NICE, but this should be clarified.	Thank you for your comments. The use of human growth hormone in children is covered by Technology Appraisal 188. No changes to the recommendation are needed.

No response received from:

Manufacturers/sponsors	General
• BioPartners (somatropin) • Ipsen (somatropin) • Merck Serono (somatropin) • Novo Nordisk (somatropin) • Pfizer (somatropin)	• Allied Health Professionals Federation • Board of Community Health Councils in Wales • British National Formulary • Care Quality Commission • Department of Health, Social Services and Public Safety for

Patient/carer groups

- Afiya Trust
- Black Health Agency
- Equalities National Council
- Genetic Alliance UK
- Muslim Council of Britain
- Muslim Health Network
- Prader-Willi Syndrome Association
- Restricted Growth Association
- South Asian Health Foundation
- Specialised Healthcare Alliance

Professional groups

- British Geriatrics Society
- British Society for Paediatric Endocrinology and Diabetes
- Royal College of General Practitioners
- Royal College of Nursing
- Royal College of Paediatrics and Child Health
- Royal College of Pathologists
- Royal Pharmaceutical Society
- Royal Society of Medicine
- Society for Endocrinology
- United Kingdom Clinical Pharmacy Association

Others

- Department of Health
- NHS Birmingham CrossCity CCG
- NHS England
- NHS Harrow CCG
- Northern Ireland
- Healthcare Improvement Scotland
- Medicines and Healthcare Products Regulatory Agency
- National Association of Primary Care
- National Pharmacy Association
- NHS Alliance
- NHS Commercial Medicines Unit
- NHS Confederation
- Scottish Medicines Consortium

Comparator manufacturers

- None

Relevant research groups

- Cochrane Metabolic and Endocrine Disorders Group
- MRC Clinical Trials Unit
- National Institute for Health Research

Assessment Group

- Assessment Group tbc
- National Institute for Health Research Health Technology Assessment Programme

Associated Guideline Groups

- National Clinical Guideline Centre

Associated Public Health Groups

- Public Health England
- Public Health Wales NHS Trust

• Welsh Government	

GE paper sign-off: Janet Robertson, Associate Director – Technology Appraisals Programme

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