From: [redacted] [redacted] [redacted]@sph.nhs.uk]

Sent: 07 January 2010 17:07

To: Jeremy Powell

Subject:Commentary on ACD - Growth

Dear Jeremy,

Here is the response from CSAS to the review of NICE TAG 42 on Growth Failure in Children on behalf of NHS Birmingham East and North – NHS BEN (which replaced NHS Wirral as consultee).

Headline response

There is insufficient evidence of cost-effectiveness to justify the use of growth hormone in children with any of the conditions listed – with the exception of demonstrated growth hormone insufficiency.

Summary

In the TAR base case only the use of somatropin for growth failure associated specifically with growth hormone deficiency achieved an ICER of less than £30,000 per QALY. Somatropin use for growth failure in other conditions arrived at ICERs of more than £30,000 per QALY in the base cases. Even after reductions in BNF prices were taken into account for the ACD, the ICERs were still greater than £30,000 for all conditions apart from growth hormone deficiency and the actual evidence of clinical benefit (particularly of improvements in quality of life associated with TREATMENT) was too limited to justify any increase in the ICERs.

Although the Appraisal Committee considered that the full disutility associated with growth failure and full utility gain from somatropin treatment had not been captured in these analyses,

this does not appear to be based on actual studies of change in utility associated with the sort of likely gain in final adult height (3.3cm) due to treatment, as estimated by some studies. Furthermore, there was limited evidence of the impact of growth hormone treatment on final adult height and a lack of direct evidence demonstrating the impact of height increase due to growth hormone treatment on quality of life in childhood. We note the comments by other consultees, particularly the British Society for Paediatric Endocrinology and Diabetes (BSPED), the Royal College of Paediatrics and Child Health (RCPCH), and the Royal College of Physicians, and we agree that the evidence of clinical effectiveness of growth hormone in most conditions (particularly Small for Gestational Age) does not demonstrate that treatment with growth hormone produces worthwhile improvements in quality of life. Similarly, we agree that there are too many inappropriate assumptions contained within the economic models – particularly regarding the values attributed to quality of life associated with the estimate minimal increase in final adult height. This is particularly important in patients whose only diagnosis is "small for gestational age", which is an epidemiological definition based on the position of the patient's height within a normal distribution, and where there is limited evidence of the impact of treatment on final adult height and no direct evidence of improvements in quality of life associated with treatment-associated height gain.

CSAS and NHS BEN note that the studies that examined growth hormone treatment for patients small for gestational age, did not use doses of growth hormone licensed in the UK. It would therefore not be appropriate to use these studies to make recommendations based upon use of growth hormone within its licence.

Yours sincerely,

[redacted]

[redacted]

[redacted]

Commissioning Support Appraisals Service

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From: [redacted]

Sent: 12 October 2009 17:19

To: 'jeremy.powell@nice.org.uk'; 'TACommB@nice.org.uk'

Cc: 'nina.pinwill@nice.org.uk'; [redacted]; [redacted]; [redacted]

[redacted]

Subject: Commentary on HTA

Dear Jeremy,

As agreed earlier today with [redacted], please find attached commentary on the Human Growth Hormone Treatment for Children.

Don will be around tomorrow, should you want to follow up with any questions.

We hope this is helpful.

Kind regards

[redacted]

[redacted]

[redacted]

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