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Sent by email to [redacted]@solvingkidscancer.org.uk

30 August 2016

Dear [redacted] and [redacted]

Final Appraisal Determination: Neuroblastoma (high risk) – dinutuximab (maintenance after therapy) [ID 799]

Thank you for your letter of 19 August, responding to my initial scrutiny letter of 5 August. I have considered the additional points you raise and can now let you have my final scrutiny decision.

Ground 1 (a)

1.1 Dinutuximab (Unituxin) should have been appraised through the Highly Specialised Technologies Programme. I have considered the clarification and further points which you make but do not consider this a valid appeal point. First, the decision to refer a topic to NICE and whether this is considered through a standard appraisal methodology or through the highly specialised technology

rests with Ministers. NICE provides advice but it is for Ministers to decide whether to refer a topic and if so which route to choose. NICE is then bound to follow that referral.

Second, although the processes may be similar for preparing advice to Ministers on single (or multiple) technology appraisals and highly specialised technologies, they are not the same. Potential highly specialised technologies are identified and put forward by the Department of Health on the basis of different selection criteria. The Department then works with NICE and NHS England in preparing the scope. NICE does not have a free hand in allocating technologies between appraisal methods as your letter and argument implies.

Third, the appeals process relates to the assessment of a technology once it has been referred. I do not think the Block Scoping Report can be said to form any part of the appraisal itself, and so it cannot be within the scope of an appeal. If there are concerns about the selection of a topic and its scope, these need to be challenged at the time. As I mentioned in my earlier letter, the scope for the appraisal under the single technology appraisal methodology was consulted upon and generally agreed at the start.

1.2 NICE unfairly failed to apply its end of life criteria. I do not consider this a valid appeal point for the reasons set out in my letter of 5 August.

1.3 The analysis of ANBL0032, and specifically the resultant use of a 10-year cure point, was inadequately explored. The points in your letter of 19 August relate to the points I made in relation to the ground 2 appeal on this issue. I do not consider this to be a valid point under ground 1(a) for the reasons set out in my letter of 5 August.

Ground 1 (b) NICE has exceeded its powers

I consider this a valid appeal point. I am pleased that you will be supplying a written submission on the issue by 26 August.

Ground 2

2.1 Dinutuximab should have been appraised through the Highly Specialised Technologies Programme. I do not consider this a valid appeal point for the reasons set out above and in my letter of 5 August.

2.2 It was unreasonable for the Institute to use a 10-year cure point given the evidence before it. I consider this a valid appeal point on the basis of the arguments set out by Dr London in your letter – specifically that the confidence intervals at the 10 year point are very wide and there is therefore too much uncertainty for it to be used for decision making.

In summary, I consider that there are two valid appeal points:

- Ground 1(b) that NICE exceeded its powers for the reasons set out in your initial letter; and
- Ground 2 that NICE acted unreasonably in choosing the 10-year cure point for the reasons set out in your letter of 19 August 2016

As I indicated in my earlier letter, these points will be heard orally. I understand the secretariat have already been in touch with you about the arrangements.

Yours sincerely

Andy McKeon
Vice chair
National Institute for Health and Care Excellence