National Institute for Health and Clinical Excellence

Monday 25th June 2007

Dear [redacted]

Final Appraisal Determination: Cetuximab for the treatment of locally advanced squamous cell cancer of the head and neck (LA SCCHN)

Thank you for lodging the Mouth Cancer Foundation's appeal against the above Final Appraisal Determination (FAD).

Introduction

The Institute's appeal procedures provide for an initial scrutiny of points that an appellant wishes to raise, to confirm that they are at least arguably within the permitted grounds of appeal. The permitted grounds of appeal are:

- Ground 1: The Institute has failed to act fairly and in accordance with its published procedures as set out in the Institute's Guide to the Technology Appraisal Process.

- Ground 2: The Institute has prepared guidance which is perverse in the light of the evidence submitted.

- Ground 3: The Institute has exceeded its powers.

This letter sets out my initial view of the points of appeal you have raised: principally whether they fall within any of the grounds of appeal, or whether further clarification is required of any point. Only if I am satisfied that your points contain the necessary information and arguably fall within any one of the grounds will your appeal be referred to the Appeal Panel.

You have the opportunity to comment on this letter in order to elaborate on or clarify any of the points raised before I make my final decision as to whether each appeal point is referred on to the Appeal Panel.

Initial view

You have one point of appeal under Ground 1 (appeal point 1) and three under Ground 2 (which I have numbered appeal points 2, 3 and 4).

I regard your appeal point 1 as a valid appeal point under Ground 1 in order to check whether the Mouth Cancer Foundation's comments were recognised as such and afforded the importance they deserve.

I am not at present persuaded that your appeal point 2 is a valid appeal point. The consultees and commentators in this appraisal were selected from the list in the Institute's Guide to the Technology Appraisal Process. Nor am I persuaded at present that your appeal point 4 is a valid appeal point. The Institute's task is to make a judgment as to whether, on balance, the treatment can be recommended as a cost-effective use of NHS resources. It would be an abdication of their responsibilities in this regard to allow cetuximab to be made available while the evidence to refine its indications for use is collected. On the other hand, I think that your appeal point 3 may be valid if it is expressed in terms of an alleged failure on the part of the Appraisal Committee to give sufficient weight to the side-effects of carboplatin, leading to a FAD that is perverse in the light of the evidence submitted.

Preliminary conclusion

My initial view, therefore, is that your appeal points 1 and 3 are valid appeal points, provided that you agree that appeal point 3 may be expressed as set out above. I regard your appeal points 2 and 4 as invalid, however. I should be grateful to receive any further comments you may wish to make before I reach my final decision. These should be sent to NICE within three weeks of the date of this letter (COB Monday 16th July 2007).

Yours sincerely

Mark Taylor
Appeals Committee Chair