

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 Merck Serono'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 six points of appeal under Ground 1 (appeal points 1 to 6), two under Ground 2 (appeal points 7 and 8) and one under Ground 3 (appeal point 9).

Appeal point 1 concerns the lack of a scoping stage for this appraisal and is a valid appeal point. Appeal point 3 relates to an alleged failure to consider relevant information and is also a valid appeal point. Appeal points 2, 4, 5 and 6 allege a lack of transparency and I regard all but appeal point 6 as valid appeal points. I am not at present persuaded that appeal point 6 is a valid appeal point. The first part of your complaint seems to be no more than a basic disagreement with the outcome of the appraisal and the second part of your complaint is un-particularised. In any event, Ground 1 refers to the Institute's published procedures as set out in its Guide to the Technology Appraisal Process.

Of your two Ground 2 appeal points, I am satisfied that appeal point 7 is a valid appeal point, but not appeal point 8. The fact that [REDACTED] considers that it would be impossible to secure agreement on trial design and/or funding is but his own view and cannot, it seems to me, render the Appraisal Committee's recommendation perverse.

I am not at present persuaded that your appeal point 9 is a valid appeal point under Ground 3. You allege that the Appraisal Committee strayed from its brief by defining treatment pathways for the treatment of LA SCCHN. However, it is not clear to me that paragraph 4.10 of the FAD does this at all and, in any event, the paragraph is written in the context of the Appraisal Committee's recommendations in respect of cetuximab in combination with radiotherapy and as a treatment for patients with contraindications to cisplatin.

Preliminary conclusion

My initial view, therefore, is that your appeal points 1, 2, 3, 4, 5 and 7 are valid appeal points and your appeal points 6, 8 and 9 are invalid. 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 16th July 2007).

Yours sincerely

Mark Taylor
Appeals Committee Chair