05 October 2006

Mr [redacted]
Manager of Health Technology Assessment and Health Economics
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Dear [redacted]

Final Appraisal Determination: Bevacizumab and Cetuximab for Metastatic Colorectal Cancer

Thank you for your letter dated 5 September, lodging your 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 set 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 appealed under Ground 2, asserting that the Institute has prepared guidance which is perverse in the light of the evidence submitted. As the Institute's "Guidance for Appellants" makes clear, to be "perverse" means to be obviously and unarguably wrong, to be in defiance of logic or so absurd that no reasonable Appraisal Committee could have reached such conclusions. Appellants should not therefore appeal on this ground simply because they disagree with the views or conclusions expressed in the FAD.

The basis for your appeal appears to be that you consider Erbitux to be a cost effective treatment in a third line setting.

In support of your contention, you make a number of specific points which I shall take as your appeal points.

1. *Position of Erbitux within the treatment pathway of mCRC.*

   Notwithstanding the wording of the Erbitux SPC, this appears to be a valid appeal point.

2. *NICE estimate of Best Supportive Care.*

   This is a valid appeal point.

3. *The need for a third line treatment in mCRC.*

   It is clear from the FAD that the Appraisal Committee considered evidence from a number of sources, including clinicians and patients. Unless you are able to explain more fully why you consider that the Institute has prepared guidance which is perverse in the light of the evidence before it (my emphasis), I am not minded to allow this as a valid appeal point.

4/5. *The continuation rule.*

   If your points 4 and 5 are taken together, I regard this as a valid appeal point.

6. *Erbitux economic data.*

   This is a valid appeal point.

7. *Erbitux budget impact.*

   This is a valid appeal point.

8. *Proposed Merck partnership with the NHS.*

   I do not regard this as a valid appeal point. It does not address why you consider the guidance to be perverse in the light of the evidence before the Appraisal Committee.

9. *Clinical advocacy.*

I do not regard this as a valid appeal point. It does not address why you consider the guidance to be perverse in the light of the evidence before the Appraisal Committee.

Preliminary Conclusion

My initial view, therefore, is that whilst your points numbered 1, 2, 4 and 5 (taken together), 6 and 7 are valid appeal points, your points numbered 3, 8 and 9 are not arguable under Ground 2 or under either of the two other grounds of appeal. 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 me within 3 weeks of the date of this letter.

Yours sincerely

[redacted]
Appeals Committee Chair