05 October 2006

Mr [redacted]
Chief Executive
Bowel Cancer UK
7 Rickett Street
London
SW6 1RU

Dear [redacted]

Final Appraisal Determination: Bevacizumab and Cetuximab for Metastatic Colorectal Cancer

Thank you for your email of 5 September, lodging Bowel Cancer UK's and CancerBackup'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 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.

You indicate that these treatments have proven benefits for CRC patients in the advanced stages of the disease, but it appears from my reading of the FAD that the Appraisal Committee have accepted that both drugs demonstrate some evidence of clinical effectiveness – see, for example, paragraphs 4.3.4 and 4.3.7 of the FAD. You go on to assert that patients who have the potential to benefit from these treatments should be allowed to receive them and those who have responded to them should be allowed to continue to receive them. I fail to see this as anything other than a statement of your own point of view and I do not know what perversity you are pointing to in the FAD. In any event, the Appraisal Committee have recommended that patients currently receiving the drugs should have the option to continue therapy until they and consultants consider it appropriate to stop – see paragraph 1.3 of the FAD – and for patients not currently receiving the drugs, it should be remembered that the Institute's guidance does not override clinical judgment.

There might be more for the Appeal Panel to consider in your assertion that the Appraisal Committee has incorrectly viewed Erbitux as a second line treatment of the disease. If you wish to pursue this point, could you please explain why this is so and what perversity you think that it is has led to.

Preliminary Conclusion

My initial view is that none of these points is 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 and I should particularly welcome hearing from you in relation to Erbitux as a second line treatment. Your comments should be sent to me within 3 weeks of the date of this letter.

Yours sincerely

[redacted]
Appeals Committee Chair