National Institute for Health and Clinical Excellence

Monday 25th June 2007

Dear Sirs,

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 Royal College of Radiologists' 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 two points of appeal under Ground 2 (appeal points (a) and (b)) and two under Ground 3 (appeal points (c) and (d)).

I am satisfied that appeal points (a) and (b) are valid appeal points. However, I am not at present persuaded that your appeal points (c) and (d) are also valid.

With regard to appeal point (c), I do not read the FAD as advocating single agent carboplatin as the treatment of choice for patients of good performance status considered unsuitable for cisplatin chemoradiotherapy. The FAD makes no recommendations in this regard. Rather it notes that carboplatin is being used to treat LA SCCHN in UK clinical practice and has an evidence base for its use in chemoradiotherapy.

With regard to appeal point (d), I cannot see how the Institute can be said to have exceeded its powers in recommending further research, whether or not one of the clinical specialists considers that it would be impossible to secure agreement on appropriate trial design and/or funding.

I shall draw your postscript to the Appeal Panel's attention, though I am not treating this as a separate appeal point.

Preliminary conclusion

My initial view, therefore, is that your appeal points (a) and (b) are valid appeal points and your appeal points (c) and (d) 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