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Roche products Ltd

19 May 2009

Dear Sirs

Final Appraisal Determination: Bevacizumab (first line) sorafenib (first and second line) sunitinib (second line) and temsirolimus (first line) for the treatment of advanced and/or metastatic renal cell carcinoma

Thank you for lodging your appeal against the above Final Appraisal Determination.

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 ("valid"). 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 should be referred on to the Appeal Panel.

Initial View

Ground one: Procedural Unfairness

1 Decision improperly based on overall affordability

I agree this is a valid appeal point. I note that you raise the point also under ground 3. It seems to me that the argument under ground 3 is that the supplemental guidance necessarily is based on affordability, and that the argument under this ground is that even if the supplemental guidance is not based on affordability, the way in which it was in fact applied in this case amounted to a decision on affordability.

2 Interpretation of the Supplementary Advice lacks transparency and is unfair.

I agree this is a valid appeal point as regards cumulation of patients with different conditions treated or treatable with the same drug. I should draw your attention to paragraph 3.2 of the supplemental guidance, which may be what the Committee had in mind when adopting its approach.

3. The basis for the committee's conclusions with regard to tolerability of bevacizumab plus IFNa is unclear.

Whilst this is a valid appeal point, I am not clear that it is a ground one point as opposed to a ground two point (and indeed you have raised the same concern under that ground). A partial reason for not recommending bevacizumab is given. If that reason is not reasonably sustainable on the evidence an appeal would be allowed under ground two, and if the reason turns out to be based on evidence you have not seen, an appeal would be allowed on ground one.

Perhaps you could expand on this point before I make a final decision

Ground two: perversity

4 The conclusions reached on the side effect profile of bevacizumab plus IFNa are perverse

I agree this is a valid appeal point.

Ground three: illegality

5 Decision improperly based on overall affordability

As noted above, I agree this is a valid appeal point.

As I am minded to rule that at least some of your appeal points are valid, I will pass your appeal to the Appeal Panel for consideration.

If you wish to make any further comment on the point that I have indicated that I do not, at this preliminary stage, view as valid, please let me have these within ten working days from the date of this letter (Wednesday 3 June 2009). I will then reach a final decision on the validity of those points.

Yours sincerely

[redacted]

Appeals Committee Chair
National Institute for Health and Clinical Excellence