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Sent by email

[redacted]
Wyeth Pharmaceuticals

19 May 2009

Dear [redacted]

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

1.1 Inconsistent use of economic models.

I cannot at present see any requirement in the Methods Guide to use on economic model for all products in the same appraisal? If anything I would have thought it was a necessary implication of allowing manufacturers to submit their own models that that model would be taken into account and might be adopted as "the" model for that product, and, if a manufacturers model was adopted, that the result would be different products were appraised using different models?

I am afraid I particularly do not understand how it can have been unfair to you for the committee to use a model you yourselves submitted?

At present I am not minded that this is a valid ground of appeal.

1.2 Failure to consider the size of the patient population.

I suspect it will be common ground that the supplemental guidance does not address the position of ultra orphan drugs as such.

Whether or not it might be desirable to have a separate process or a specific set of criteria for ultra orphan drugs, it cannot as such be a ground of appeal that this has not been done. Arguments based on the mere fact that there are few affected patients would also, in effect, be arguments that there should be a special regime for ultra orphan drugs, and so not valid. However you rightly point out that there is not a fixed threshold for cost effectiveness in any appraisal, and that the features of the population are a relevant consideration.

Provided care is taken to focus on the appraisal process as it stands, I agree this is a valid ground of appeal.

1.3. Failure to consider the degree of clinical need

I find it difficult to see that the committee did not consider clinical need for patients with poor prognosis, in light in particular of the discussion at FAD para 4.3.11 et seq. I do not agree there is a need for an "explicit" value judgement provided clinical need is clearly taken into account.

At present I would not be minded to allow this appeal point to proceed.

Ground two: perversity

2.1 That it was perverse not to consider the End of life supplementary guidance in the context of the results from the assessment group's model.

Although I was not persuaded this was a valid process point, I agree it is a valid perversity point.

Conclusion

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 points 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