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[redacted]
James Whale Fund for Kidney Cancer

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 Bevacizumab

Although I can understand why you have described your complaint as a matter of fairness, it seems to me that it relates to the treatment of the evidence by the committee. Essentially you say you cannot assume that tolerability of a Bevacizumab plus IFNa regime is the same as an IFNa regime because there is the opportunity to reduce the IFNa dose.

That would be a perversity argument, i.e. that the evidence was not reasonably capable of supporting the conclusion reached.

I would be minded to agree this is a valid appeal point, but under ground two.

2 Sunitinib

For essentially the same reason given above, I would be minded to agree this is a valid appeal point, but under ground two rather than ground one.

3. Temsirolimus

Although I fully understand the point you are making about this patient group, I am not sure how it relates to the permitted grounds of appeal. I would be grateful if you could give me more detail on the point you want to argue. The difficulty would be that it is not for the appeal panel to substitute its judgement for that of the committee. Your appeal seems to be that the committee should have been more lenient for patients with a poor prognosis and no other treatment options. Of course I can readily understand that point of view but it is not without more a ground of appeal that an appeal panel could uphold.

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

4 Sorafenib (also raised under ground two)

If it transpires that evidence has not been taken into account at all, that would be a valid ground one complaint. However I cannot see from the FAD that there is a prospect of successfully arguing this evidence was ignored altogether. If evidence was taken into account but not found persuasive, that could only be challenged if that judgement was perverse.

I would therefore be minded to allow this appeal point to go forward under ground two only.

Un-numbered point

It seems to me that this point takes issue generally with the consequence of the guidance. Again I can understand your point of view but do not think there is at present anything here that an appeal panel could find to be a valid ground of appeal. You would need to give a reason for the consequences being based on unfairness, or perverse. Furthermore, I think your complaint bears on the overall pathway of care for these patients, but it is not the function of a technology appraisal to recommend a pathway of care. Instead the appraisal is limited only to the specific technology and indications provided for in the scope. It would be for a clinical guideline to recommend a pathway of care.

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

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, or on my proposed reallocation of some of your appeal points to ground two, 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