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Sent via email

Dr Pat Hanlon
KCUK Trustee
Kidney Cancer UK

17 December 2010

Dear Dr Hanlon

Final Appraisal Determination: Everolimus for the second line treatment of advanced and/or metastatic renal cell carcinoma

Thank you for lodging Kidney Cancer UK's 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
- Ground 2: The Institute has formulated guidance which cannot reasonably be justified 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.

I can confirm that there will be an oral hearing of the appeal.

Initial View

Ground 2

Your argument is that the average survival time for patients receiving BSC cannot reasonably be said to be 10.8 months, and that as a result the difference in overall survival between patients receiving BSC and patients receiving everolimus cannot be 5.9 months.

I agree this is a valid ground two appeal point, but would comment (as I think you agree) that the relevant issue must surely be the reasonableness of the value for the difference in survival, as this is what feeds into considerations of cost effectiveness. You should anticipate that the appeal panel may focus on that point.

Conclusion

As I am minded to rule that your appeal point is valid, I will pass your appeal to the Appeal Panel for consideration.

If you wish to make any further comment please provide to me this within 10 working days from the date of this letter (omitting the 2-week Christmas holiday period), no later than **Monday 17 January**.

Yours sincerely

Maggie Helliwell

Appeals Committee Chair

National Institute for Health and Clinical Excellence