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Rarer Cancers forum

Macmillan Cancer support

11 June 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 your response to the initial scrutiny of your appeal lodged against this FAD. This letter represents the final decision on initial scrutiny.

Point 2

Although I have carefully considered your additional arguments, I am afraid I am still not persuaded this is a valid point. Whether or not it was correct to ask the Institute to appraise temsirolimus would have to be a matter for the Department of health and not the Institute. The committee cannot be criticised for having carried out the appraisal in accordance with the published procedures. I take your point that there is flexibility to give more favourable consideration to ultra orphan drugs, (or indeed to any other drug, if the facts of an appraisal suggest it) but I cannot see that it would be a valid appeal point if this was not done here. Furthermore, the supplemental guidance on end of life treatments, which was applied, seems to me to go some way towards taking a more flexible approach in these cases.

Point 3

As there are no further comments I confirm my decision that this is not a valid appeal point.

Point 4

I am afraid I do not agree this is a valid appeal point. The FAD is clear that sunitinib is not recommended for any patient population. I do not understand the relevance of patients who may have

received a tyrosine kinase inhibitor in a clinical trial. The FAD would treat those patients in the same way as any other patients, i.e. it does not recommend treatment with sunitinib.

Conclusion

This is the final decision on initial scrutiny. The valid appeal point is point 1, under ground one or ground two.

Yours sincerely

[redacted]

Appeals Committee Chair

National Institute for Health and Clinical Excellence