Response to the Appraisal Consultation Document:
Bevacizumab, sorafenib, sunitinib (second-line) and temsirolimus for the treatment of advanced and/or metastatic renal cell carcinoma

March 2009

This response is submitted on behalf of:

- Macmillan Cancer Support
- The Rarer Cancers Forum

We are extremely disappointed that the recently issued ACD on the use of bevacizaumab, sorafenib, sunitinib (second-line) and temsirolimus for the treatment of advanced and/or metastatic renal cell carcinoma is negative and we do not feel that the preliminary recommendation reflects the needs of this small patient group.

1. **Do you consider that all of the relevant evidence has been taken into account?**

   1.1. Point 4.3.2 in the ACD states "there are no second-line treatment options". Therefore the treatments considered in this appraisal provide new options for people once they have exhausted first-line treatment. The innovation that these four therapies bring to the treatment of advanced and/or metastatic renal cell carcinoma is significant and we would urge the Appraisal Committee to reconsider its decision, particularly for second-line therapies.

   1.2. It seems to us that because there have been no pharmaceutical developments in advanced and/or metastatic renal cell carcinoma since interferon came to the market, these four treatments are at a disadvantage because the comparator is old and comparatively inexpensive.

2. **Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence, and that the preliminary views on the resource impact and implications for the NHS are appropriate?**

   2.1. Point 4.3.12 notes that "temsirolimus was licensed for people with a poor prognosis and so had a very small patient population". The budget impact to the NHS of this treatment is likely to be extremely small. It is vital that NICE is able to take wider budget impact in to account in its analysis to ensure that important treatments like these are made available to those patients who would benefit from them.

2.2. In relation to point 4.3.6 of the ACD, we hope that the discussions between the manufacturer of bevacizumab and the Department of Health are concluded in time for the next Appraisal Committee meeting so that revised cost effectiveness estimates for this treatment can be considered in the analysis.

2.3. Point 4.3.21 states "It considered that the magnitude of additional weight that would need to be assigned to the original QALY benefits in this patient group for the cost effectiveness of the drug to fall within the current threshold range would be too great." Please could you explain what the magnitude of additional weight would need to be to have made this acceptable within the new end-of-life guidance?

2.4. We are disappointed that the patient access schemes offered by the manufacturers do not reduce the cost effectiveness assumptions sufficiently to make these treatments available within the NHS. We would urge all of the manufacturers to look again and see if there is more that they can do make the cost effectiveness of these treatments acceptable to Appraisal Committee.

3. Do you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS?

3.1. We do not consider that the provisional recommendations constitute suitable guidance to be implemented by the NHS.

3.2. This appraisal highlights methodological flaws in the technology appraisal process. A drug which clinicians believe is effective – when there are no other equivalent treatment options – should be recommended.

4. Are there any equality related issues that need special consideration that are not covered in the ACD?

4.1. Point 4.3.8 states "the Committee noted that bevacizumab was also licensed for a number of other indications involving much larger patient groups." We are concerned that the Appraisal Committee has interpreted the '*Appraising life-extending, end of life treatments'* guidance in this way. We believed that only the indication of the treatment being appraised would be considered in this new guidance rather than additional licence indications which a manufacturer holds for the same product. We believe that this interpretation of the additional guidance could disadvantage small groups of patients with conditions at the end-of-life and that this interpretation is not in the spirit of the additional guidance. We would therefore urge the Appraisal Committee to reconsider the bevacizumab analysis using the new guidance for end-of-life medicines.

5. Other comments

5.1. We are pleased that the Appraisal Committee was able to approach this appraisal pragmatically and allow sunitinib for the first-line treatment of advanced and/or metastatic renal cell carcinoma to be considered separately from the rest of this appraisal.

5.2. However, as charities dealing with patients and their families being denied treatment for kidney cancer, we are more than disappointed that the Appraisal Committee is minded to reject all of these treatments, which could make a significant impact on patients' lives, relieving symptoms and maintaining function.

5.3. We believe that these treatments should be made available to those that would benefit from them, on the basis of clinical decision making, rather than on purely cost effectiveness grounds.