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

August 2008

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 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.

i) Do you consider that all of the relevant evidence has been taken into account?

We do not think that interferon alpha is a suitable comparator because the side effect profile is so significant that many patients cannot tolerate this treatment. In the materials for the meeting on 9th July it was deemed inappropriate for interferon to be used in clinical trials. If this is the case then what treatments would be available to renal cell carcinoma patients if NICE does not approve any of the treatments it is currently assessing?

Point 2.4 in the ACD states "There is no standard treatment for people with advanced and/or metastatic RCC whose condition does not respond to first-line immunotherapy, or for people who are unsuitable for immunotherapy." Therefore, these treatments provide new options for patients who have exhausted and/or are unsuitable for immunotherapy. We would urge the Committee to re-consider this group of patients in the analysis.

The NICE Technology Appraisal process produces barriers to innovation. Whilst we understand that innovation per se is not valued within the NICE system in certain circumstances, like this one, the innovation that these four therapies bring to the treatment of advanced and/or metastatic renal cell carcinoma is significant and should be considered by the Appraisal Committee.

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 fours treatments are at a procedural disadvantage because the comparator is old and comparatively inexpensive.

We welcome the risk-sharing agreements that the manufacturers of two of these technologies have put forward, and would urge the Committee to reconsider their decision once the Department of Health has concluded its discussions with these manufacturers. In addition we would urge manufacturers to put forward risk-sharing agreements which reduce the QALY to make these treatments more likely to be considered cost effective.

ii) 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?

We are concerned that the EQ5D measure of quality of life does not have a dimension which adequately captures energy or fatigue. These are very important considerations in treatment for cancer patients, particularly as their disease progresses and must be considered by the Appraisal Committee.

Point 4.1.23 notes that, “Although promising, data on overall survival are in general immature.” A system must be put in place to make appropriate decisions when data is immature. If NICE begins to make decisions quicker and closer to product launch it is important that cancer treatments are not routinely turned down due to immature data, so safeguards must be put in place to reduce the potential for this to happen.

We are also concerned that when clinical trials allow patients to cross over to the other arm of the trial because of ethical issues, this degrades the clinical trial data, as described in point 4.1.24. This makes the data less compelling because end points are not reached in the control arm. We would ask the Appraisal Committee to consider this important clinical trial data again.

iii) 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?

We do not believe that the provisional recommendation constitutes suitable guidance to be implemented by the NHS.

This appraisal highlights methodologically flaws in the technology appraisal process. A drug which clinicians believe is effective – when there are no other equivalent

treatment options – should be recommended. We have described other methodological concerns above.

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

The recent NICE Citizen's Council report recommends that NICE and its advisory bodies should take the severity of a disease into account when making decisions. We would like to see, in the 'Evidence and interpretation' section, whether the Appraisal Committee was persuaded in this instance to take the severity of this condition into consideration alongside the cost and clinical effectiveness evidence.

v) Other comments

As a group of charities dealing with patients and their families being denied treatment for kidney cancer, we are more than disappointed that the committee is minded to reject all of these treatments which are vital to patients.

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.