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Chris Feinmann
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26th November 2008

Dear Mr Feinmann

Re: Bevacizumab, sorafenib, sunitinib and temsirolimus for the treatment of advanced and/or metastatic renal cell carcinoma - additional analyses for consultation

I write on behalf of the NCRI/RCP/RCR/ACP/JCCO in relation to the above consultation. We are grateful for the opportunity to respond and would like to make the following comments which have been coordinated by our experts [redacted] and Dr David Chao across the NCRI Renal Cancer Clinical Studies Group:

- The Appraisal Committee feel that it is not plausible that the "overall survival of people who only received sunitinib was now higher than those people who received sunitinib as well as further treatments" (p50). However, clinically it is entirely reasonable that those people who received sunitinib only do much better than those who had further treatments. This critical issue has arisen because the trial has effectively selected for the group of patients who responded well to sunitinib, whereas the group requiring second line therapies would be expected to have more aggressive disease and a less good prognosis. It led the Committee to reject using the sunitinib data from the "no post study treatment group" and instead use the data from the full ITT population.

- Why the difference in cost of drugs (Pfizer vs PENTAG)?

- We note new guidelines to be published in 2009 on 'End of Life' medicines for conditions with less than 7,000 patients/year incidence, less than 2 years expected survival, and expected substantial improvement in survival with the new treatment. These criteria are certainly relevant to this appraisal.

- Interferon should not be considered UK standard treatment for all patients - in some patients there is no effective therapy available.

- The recently published paper by Mike Richards, "Improving Access to Medicines for NHS Patients" is highly pertinent. We would value clarification from the Committee on how its recommendations are consistent with the following recommendations made in the paper which have been accepted by the Minister for Health:

  Recommendation 1: Timeliness of NICE decisions

  Recommendation 5: The DH should work with NICE to "make available drugs used near the end of life which do not currently meet the cost-effectiveness criteria currently applied to all drugs"

Recommendation 6: "The DH should urgently undertake further work to investigate the extent and causes of international variations in drug usage"

We hope that a decision can be taken as soon as possible (since there is now even more inequity across the UK in PCT funding decisions) and would hope that professional and consumer experts will be invited to attend the final meeting in January.

I trust these comments will be of use.

Yours sincerely