Royal Free Hampstead NHS
NHS Trust

Bevacizumab, sorafenib, sunitinib and temsirolimus for the treatment of advanced and/or metastatic renal cell carcinoma

RESPONSE TO NICE APPRAISAL CONSULTATION DOCUMENT JULY 2008

Dear Sir,

I have reviewed the Appraisal Consultation Document of July 2008 and I am both disappointed and frustrated at the provisional recommendations of the committee. I wish to make the following points under the headings given in the instructions,

(1a) I do not consider that all the clinically relevant data has been taken into account. Firstly, the post hoc subgroup analysis of patients in the Sunitinib vs Interferon Trial who did not proceed to have any second line therapy is highly relevant and while I accept that this was late-breaking news an opportunity should be given for this information to be assimilated by the health economic team and for any further information to be provided by the company before any recommendation is made.
(1b) Secondly, I highlighted that there was "real world" data on Sunitinib available through the Expanded Access Program run by Pfizer and this information, while not randomised clinical trial data, is relevant and important to underpin the efficacy of the treatment.
(1c) I do not believe that evidence from the patient groups has been properly considered in the decision making process. It was apparent from the NICE meeting that comments from their representatives would not or could not be taken into account and that cost effectiveness would be the sole criterion. I find it very hard to believe that Professor Littlejohns can say publicly on the BBC that cost-effectiveness was not the sole criterion when it so obviously is.

(2a) It is not possible for me to say whether the health economic model as presented by PENTAG is valid or not as this is a highly specialist area of statistics. Clearly there are areas of disagreement between the models presented by PENTAG and by the companies. It was not immediately apparent at the NICE meeting why PENTAG's model should be accepted as being the correct one and because this issue is of critical importance it would seem reasonable and logical that a third party adjudicates on the matter.
(2b) I do not agree that the resource implications for the NHS in its entirety have been addressed. I made the point during the NICE meeting that these drugs have been given orphan drug status because this is still a comparatively rare cancer and that therefore the resource implications for the NHS if these new treatments were to be adopted must be considerably less than if this was a common cancer. This has simply not been factored into any calculations and according to the answer given to me at the time the appraisal committee cannot do so. I would put it to the committee that since they acknowledge that these treatments are clinically effective with significant patient

benefit the committee should recommend that the impact on the NHS be reviewed fully and that these drugs should be accorded special status.

(3) I do not agree that these recommendations constitute a sound basis for preparation of guidance to the NHS. It was highlighted at the NICE meeting that all the countries with which the UK should be compared in terms of healthcare have adopted these drugs as the new standard of care for advanced kidney cancer. By denying UK patients these new drugs we will see a significant difference in survival between the UK as a whole and neighbouring countries. To add insult to injury we also make the UK less attractive for clinical trials because the forthcoming trials will all assume that these new drugs, as the new standard of care, will be widely available and funded. Patients will have a "double whammy" of being denied both the global standard of care and access to new drugs through clinical trials.

(4) It was highlighted at the NICE meeting that there is already inequality in access to these new drugs in the NHS with the post code lottery because some PCTs have agreed to fund these new drugs. There is further inequality in that these drugs can be prescribed privately. The clinical efficacy of these drugs is such that there will be significant differences in survival between those who can get the drugs over those who can't. The NHS celebrates its 60th year this year and it was created to make healthcare available to all, the most fundamental of equalities. We all recognise the need for cost effectiveness in the NHS, but this "one size fits all" is the ultimate inequality, and surely that is not what NICE should stand for.

Yours sincerely,

Dr. David Chao, BMBCh FRCP DPhil,

8th August 2008