

Dr Carole Longson
Director, Centre for Health Technology Evaluation
National Institute for Health and Clinical Excellence
MidCity Place
71 High Holborn
London
WC1V 6NA

14th December 2010

Dear Dr Longson

Re: ACD_Transitional cell carcinoma of the urothelial tract - vinflunine

I write on behalf of the NCRI/RCP/RCR/ACP/JCCO with relation to this ACD consultation. We are grateful for the opportunity to respond and would like to make the following comments.

Has all of the relevant evidence been taken into account? Yes

Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence? Yes, provided the following comments are considered.

We believe that section 4 is largely a balanced account of the major points raised by the clinical experts present at the appraisal meeting. It also adequately covers the questions they answered. The only exception to this would be the portion of section 4.5, which states that *'vinflunine might be used more commonly as a third-line rather than a second-line treatment for advanced or metastatic transitional cell carcinoma of the urothelial tract. This is because patients whose disease relapses after a response to first-line platinum-based chemotherapy would usually receive a further platinum treatment before an alternative agent was tried'*.

We do not believe that the above statement is an adequate reflection of what was said at the meeting, nor what the UK oncology community would consider accurate. Vinflunine might well be considered a third-line choice, but more because there are other 2nd-line agents which we consider to have a therapeutic index which is as good or better, rather than the desire to use another platinum-based regimen.

Confusion may have arisen around this point due to the situation where metastatic relapse is a considerable time after platinum-based neoadjuvant chemotherapy, where one might be inclined to use 're-challenge' platinum as first-line therapy for advanced disease. The misleading statement is also repeated as one of the 'key conclusions' in the summary. On balance, we believe it would be worth correcting this.

The statement in the summary of 4.4 (bottom of page 23) states that *'Most patients in the UK receive systemic chemotherapy with radical treatment'*. This is incorrect and we strongly recommend that the word 'most' is replaced by the word 'many' (which is the word actually used in section 4.4 itself).

One important point raised by our clinical experts (and also by the experts at the appraisal meeting) was that the 302 data are imperfect but, nonetheless, are the best data available at present. This receives a tangential mention at the end of Section 4.2 and a slightly more direct one in 6.1 (as correctly stated). It may be that this point should receive greater emphasis within the FAD.

Are the provisional recommendations sound and a suitable basis for guidance to the NHS?

Yes

Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of gender, race, disability, age, sexual orientation, religion or belief? No

Are there any equality -related issues that need special consideration and are not covered in the appraisal consultation document? No

Yours sincerely

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