ovacome..

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22nd January 2013

Response to ACD: Bevacizumab in combination with paclitaxel and carboplatin for first-line treatment of advanced ovarian cancer

Dear Dr Adam and Committee,

Ovacome wishes to respond to the above ACD, which we received on the 12th December 2012.

Has all of the relevant evidence been taken into account?

We believe that all of the relevant evidence has been recorded. Naturally we wish that NICE would be able to take greater account of the issues raised and submitted by patients groups, and the innovative nature of this technology.

Dose issues.

The position of the committee; that it is unable to consider the lower dose of 7.5mg is confusing. The pre meeting briefing report states that

"The summary of product characteristics for bevacizumab states that 'the recommended dose of bevacizumab is 15 mg/kg of body weight given once every 3 weeks'. The European Medicines Agency concluded that there was insufficient evidence of an acceptable balance of clinically relevant benefit to risk at the lower dose (7.5 mg/kg) used in the ICON7 study. Therefore, NICE is unable to produce guidance for the unlicensed dose of 7.5 mg/kg."

However at the commencement of the meeting, the experts in the presence of the committee were told that the reason ICON 7/ the lower dose of 7.5 mg could not be considered was because NICE could not evaluate technologies outside of the licensed indication.

The difference in these directions is significant. At the time of license there were less available results from the ICON 7 study than at the time of the NICE meeting, thus NICE would have been furnished with a higher level of evidence to be able to determine whether there is now sufficient 'evidence of an acceptable balance of clinically relevant benefit'

During the coffee break, I raised the question of perversity of this position with regard to the verbal direction given; that NICE are unable to consider technologies outside of the licensed indication. I suggested to Meindert Boysen that it was my belief that NICE had

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considered use outside of license when it reviewed PLDH, which is licensed at 50 mgs, but in fact used at 40mgs.

Since that time, I have been unable to test the veracity of my recall as the TA in question – TA 45 has been removed from the NICE website. Similarly NICE guidance on the use of Paclitaxel in first line advocates its use in combination with Carboplatin, which is outside of licence.

TA55:

1.1 "It is recommended that paclitaxel in combination with a platinum-based compound or platinum-based therapy alone (cisplatin or carboplatin) are offered as alternatives for first-line chemotherapy (usually following surgery) in the treatment of ovarian cancer."

The licence for Paclitaxel specifies its use in combination with Cisplatin. It is clear therefore that NICE has in the past recommended treatments outside of their licensed indication, and we therefore believe that the decision not to consider non licensed dosage in this instance, given the available evidence (ICON 7) is perverse.

Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?

The ACD examines the evidence fully at the dose of 15mgs; however we would advocate that cost effectiveness/ICER data of use at 7.5 mgs be published (as it is in the SMC guidance).
Women are currently able to access Avastin (at 7.5 mgs) via the Cancer Drugs fund (CDF). The CDF ceases in March, and at present we are uncertain as to the details of its replacement. We anticipate that for the interim at least there is a possibility that clinicians may have to submit Individual Funding requests (IFR) as they currently do in Wales and Scotland. Having fuller details on the NICE determinations/ICERs at 7.5mgs, the UK preferred dose, would be useful to women in attempting to access treatment via an IFR.

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

As previously submitted, we believe that NICE may have previously issued guidance for treatments outside of the licensed indication; however this matter requires further investigation.

We believe that the guidance as it stands will cause significant distress to women affected by ovarian cancer as they perceive this treatment as being the most significant advance in the treatment of the disease in many years. There is the possibility that some will make considerable financial compromises to be able to access the treatment privately.

We believe that an unintended consequence of the guidance as it stands will be to hamper further clinical research which would lead to understanding better when and for who Avastin would be most beneficial, as well as its use in potentially more active combinations. These studies would of course make the treatment more cost effective for the NHS.

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 race, gender, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?

We believe that as a consequence of the guidance discrimination may occur.

As previously stated the current lack of a clear replacement for the CDF in England, and the lack of a CDF in the rest of the UK will see an increase in the need to use IFRs to be able to access treatments. The individual funding request is a rigorous process. It is instigated by the clinician, however in many cases this is prompted by the informed patient. We believe that patients who are not able to access detailed treatment information outside of that given by the clinical team, and unable to research the treatment options available due to poverty, age or disability will be unaware that there are alternate treatments available, nor how they might be able to access them. As a consequence we believe that the ACD will cause a difference in the way women across the UK are treated based on their age and financial status.

We have been unable to identify any research undertaken to establish whether the IFR is an intrinsically discriminatory process, however it is something that many in the cancer patient community believe to be the case.

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