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Dr Carole Longson
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22nd June 2010

Dear Dr Longson

Re: NICE Appraisal of bortezomib and thalidomide for the first-line treatment of multiple myeloma - ACD and Evaluation Report

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.

We welcome the Appraisal Committee's preliminary recommendations. Give the currents state of knowledge, we believe that this guidance offers therapy for patients with myeloma that provides the best opportunity to prolong survival and to improve quality of life.

Has all the relevant evidence been taken into account?

We recognise the flaws in some clinical trial designs that make it difficult to generalise the results and therefore to utilise the data in coming to meaningful recommendations in relation to optimal patient management. However, we agree that every effort has been made to include all relevant evidence in reaching this provisional guidance. By making these recommendations the Committee have shown that they are cognisant of the need for clinicians to select therapy that most appropriately meets individual patient circumstances and hence maximising disease response whilst minimising toxicity and side-effects.

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

We believe that the committee's summaries of the clinical and cost effectiveness have taken into account the wide variation in the results of economic analyses provided by the manufacturers and the assessment group. It is important to note that the group accepted the expert clinical advice relating to the fact that in clinical practice less vials were utilised than in the initial assessment. This has clearly impacted on the ICER for bortezomib.

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

It is important that the final guidance provided by the assessment group is clear and leaves no room for conflict between clinicians and providers. Such conflict, could lead to treatment delays or the delivery of inappropriate treatment. The word 'contraindications' as applied in para 1.2 of the guidance suggests that bortezomib is a default position from thalidomide and may disadvantage individuals at high risk of toxicity from using either thalidomide (eg if they have a past history of thrombosis or renal failure) or

bortezomib (eg if there is a history of neurological damage). We would suggest that in order to accommodate clinical decision making, the term ‘contraindicated’ should be replaced by the term ‘clinically inappropriate’.

We do, however, agree that the provisional recommendations provide a sound and suitable basis for guidance to the NHS. We believe that it offers clinicians the opportunity to use clinical judgement on an individual basis to maximise and improve outcomes for patients with this life-threatening disease whilst optimising the cost to the NHS.

Conclusions:

The recommendations have taken into consideration the available data from what is a rapidly developing field. They recognise the fact that the disease and patients are heterogeneous requiring a degree of risk adjusted therapy in order to maximise responses whilst optimising the toxicity profile of treatment combinations to enhance quality of life.

Our thanks go to our clinical expert nominee [redacted] for coordinating the response.

Yours sincerely

[redacted]