

Response on behalf of the UK Myeloma Forum, the British Society for Haematology and the Royal College of Pathologists.

Dear Dr Longson

Thank you for the invitation to comment on the Appraisal Consultation Document for the single technology appraisal of Bortezomib monotherapy for relapsed multiple myeloma issued on May 24th 2007.

The UK Myeloma Forum (UKMF), the British Society for Haematology (BSH) and the Royal College of Pathologists (RCPATH) have agreed the following joint response under the following headings:

Do you consider that all of the relevant evidence has been taken into account?

We are satisfied that the Appraisal Committee has considered the evidence available and we are particularly appreciative of the fact that the committee has taken into account the views of people with multiple myeloma, the organisations who represent them, and the clinicians who treat people with myeloma.

We understand that the complexity of the disease and the fact that different treatment approaches are required at different times and for different individuals has made this appraisal particularly challenging. We value the fact that the Appraisal Committee has recognised these factors and taken them into account in their determination.

Do you consider that the summaries of the clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and the implications for the NHS are appropriate?

We note and support the appraisal committee's conclusion that the Apex trial constitutes clear evidence that Bortezomib is more clinically effective than HDD monotherapy.

We welcome the Appraisal Committee's approach to the manufacturer's suggestion of implementing a response based stopping rule with a rebate for non responders.

This will effectively reduce the cost per QALY and we see this as a creative way of making this effective agent affordable to the NHS and thus available to patients.

Do you consider that the provisional recommendation of the appraisal committee are sound and constitute a suitable basis for the preparation of guidance to the NHS?

We welcome then Appraisal Committee's recommendation which if implemented will enable clinicians to use this effective therapy and treat patients appropriately.

We note the appraisal committee reluctance to include in the recommendation the group of people whose disease demonstrates minimal response (MR) as has been suggested by the manufacturers.

Whilst we acknowledge that as yet evidence that achievement of MR can be shown to be cost effective is not strong, we wish to record that achieving clinical improvement and arrest of progress of disease is beneficial and undoubtedly associated with prolongation of survival.

In summary our Professional bodies welcome the Appraisal Committee's recommendation which we believe to constitute a fair and constructive approach to the challenge of making Bortezomib, a major clinical advance, available to patients with Multiple myeloma which would result in improvement both in the quality and duration of their lives.

16 June 2007