MyelomaUK

informing
understanding
supporting

Leukaemia CARE
supporting a quality of life

cancerbackup

Myeloma UK, Cancerbackup and Leukaemia CARE: Joint response to the revised Appraisal Consultation Document on bortezomib monotherapy for relapsed multiple myeloma

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

1.1 As the recommendations stand in the revised ACD, all myeloma patients who are suitable for bortezomib (Velcade) will now get access to this clinically effective treatment. We absolutely support this principle.

1.2 Whilst we are pleased that this draft recommendation is positive, we remain disappointed that NICE is not able to appraise treatments outside of their licensed indication, even if the indication has fallen behind clinical practice.

To consider bortezomib as part of combination therapy would have been more clinically relevant, a point we have argued consistently throughout the appraisal. However, we do recognise this is currently beyond the powers of NICE.

1.3 The Velcade Response Scheme (VRS) was designed by the manufacturer in conjunction with the Department of Health to overcome the cost effectiveness uncertainty of bortezomib. As such we were not involved in discussions about the scheme or its design.

In terms of the design of the scheme as set out in the ACD, we accept the Committee's assertion that there is limited evidence regarding the association between magnitude of initial M-protein response and prognosis.

However, it is well accepted among treating clinicians that response to treatment should be viewed in the context of each individual patient and that the duration of response is as clinically relevant as the magnitude, especially in the presence of improvement in end-organ damage and resulting quality of life.

It therefore may not always be clinically appropriate, ethical or cost effective to deny patients access to a maximum or minimum number of treatment cycles based only on magnitude of response.

Our concern is that patients in the minimal responder (MR) group who achieve a smaller magnitude of response at four cycles as measured by M-protein would, with further treatment, achieve a long duration of stable, asymptomatic disease.

We therefore consider that the VRS should include MR so as to ensure that all benefiting patients continue to do so and are not prematurely excluded from treatment with this therapy.

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

2.1 Notwithstanding the points we raise at 1.2 and 1.3 we feel the recommendation is a fair reflection of the evidence and are pleased that bortezomib has been recognised as a clinically effective drug.

MyelomaUK

informing
understanding
supporting

Leukaemia CARE
supporting a quality of life

cancerbackup

Myeloma UK, Cancerbackup and Leukaemia CARE: Joint response to the revised Appraisal Consultation Document on bortezomib monotherapy for relapsed multiple myeloma

2.2 We do however remain disappointed that the Appraisal Committee and the manufacturer were unable to remove the uncertainty around the cost effectiveness of bortezomib without the VRS.

Nevertheless we have no doubt that the VRS is implementable and will have little or no impact on resource planning for the NHS.

2.3 We applaud the willingness and commitment of the Institute, the Department of Health and the manufacturer to making bortezomib available within the NHS and for creating an innovative solution to ensure that this important treatment can be accessed by patients.

Do you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS?

3.1 As the recommendation stands, all patients who are suitable for bortezomib will now get access to it. We absolutely support this principle and welcome that the guidance is applicable to all relapsing myeloma patients.

3.2 However as outlined in point 1.3 we have significant concerns about the appropriateness of ending bortezomib treatment for minimal responders after four cycles, as currently outlined in the VRS, and would urge the Appraisal Committee to reconsider this aspect of the guidance before issuing the Final Appraisal Determination.

Declarations of Interest

Myeloma UK receives an unrestricted educational grant from Ortho Biotech, the manufacturer of bortezomib, to use across its range of services.

Cancerbackup has received sponsorship for several publications and projects from Ortho Biotech, the manufacturer of bortezomib.

Leukaemia CARE has received limited financial support from Ortho Biotech towards the running of patient conferences in 2006, (but nothing for the current financial year); and limited support for production of generic, unbranded patient information leaflets.