

04 April 2007

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Dear Simon,

**Health Technology Appraisal
Bortezomib monotherapy for relapsed multiple myeloma**

Following the outcome of the Appeal Panel decision sent to you on 26 March 2007, I am writing to you to request confirmation of the position of the Department of Health in relation to the 'risk-sharing' arrangements proposed by Janssen-Cilag for the provision of bortezomib, within its licensed indication, for relapsed multiple myeloma, in the NHS in England and Wales.

As you are aware this appraisal is being sent back to the Appraisal Committee, where it will be discussed on 8 May 2007. In order to fully prepare for that meeting we need your response by **17 April 2007** at the latest.

We would appreciate to receive the following details of the risk-sharing arrangement together with your comments in each case:

- the patient group for whom the proposed arrangement is being created – for example, patients who have suffered a first relapse;
- the number of cycles after which response is determined – for example, 3 and/or 4 cycles;
- confirmation that the scheme is designed to be tenable for all NHS organisations in England;
- clarification on the status of the arrangement in terms of the NHS in Wales (we are writing separately to the Welsh Assembly Government, but we are aware that you wish to liaise with them on this matter);
- the duration of the arrangement and, if applicable, details of any proposed review;
- contact details of the people in the Department of Health who are involved in evaluating the proposal.

Finally, I would like confirm that we are exploring the option of appraising the (unlicensed) use of bortezomib in combination with dexamethasone separately from our further consideration of its licensed use. Because consideration of the unlicensed use of bortezomib will require a new referral, and in order to not impede the appraisal of the monotherapy (licensed) indication, the committee will not consider off-label use of bortezomib at its meeting on 8 May. The Institute is in contact with consultees on this matter and we hope to present their views on the appropriateness of undertaking a separate appraisal of the use of bortezomib for your consideration within the next month.

Please address your response to this letter to Reetan Patel, project manager, on Reetan.patel@nice.org.uk.

Yours sincerely

Carole Longson
Director, Centre for Health Technology Evaluation

CC. Andrew Dillon, Meindert Boysen, Ms Wendy Chatham