



Llywodraeth Cynulliad Cymru  
Welsh Assembly Government

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Dear Emily

**Bortezomib for Multiple Myeloma: Single Technology Appraisal (STA)**

Please find attached below the Welsh Assembly Government's comments on the above.

1. There are several important issues that need to be considered:-

- Bortezomib is undoubtedly an effective treatment for Myeloma;
- Bortezomib may work when other treatments have failed but in the UK practice is seldom used in first relapse; its precise timing is uncertain;
- There is growing evidence that Bortezomib is more effective in combination rather than as a monotherapy;
- The problems in relapsed and primary refractory Myeloma are not necessarily the same.

2. In the light of this, support is given to the decision not to endorse Bortezomib Monotherapy as the treatment of Myeloma in first relapse. The results of the study to Myeloma IX will shed a lot of light on this question and should be fully supported - but it uses Bortezomib in combination with High Dose Dexamethasone (HDD).

3. There will be a cohort of patients already in the UK who have had multiple relapses - possibly after high-dose Melphalan - or who have been shown to be refractory to several other regimes. These patients are excluded from the Myeloma IX study by their current disease status but should not be denied the chance of a worthwhile response from Bortezomib. The recommendations need to have an additional paragraph that addresses the needs of these patients and allows them the use of Bortezomib +/- HDD.



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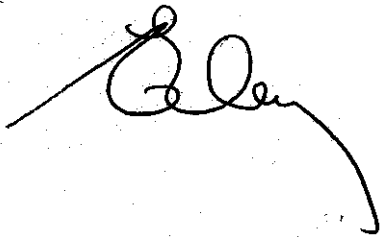
4. The draft rightly criticises the relative usefulness of Bortezomib vs Dexamethasone at first and subsequent relapse on the grounds that there are other effective and cheaper options.

5. What is still clear to clinical haematologists is that for a significant number of patients who have already received all the options (more first line treatment CTD / MP, VAD, 2nd high dose etc) Bortezomib produces a useful response. If this draft is agreed then Bortezomib will be unavailable for a large group of patients for whom it is the only prospect of another year or 2 of life. There are no trials in Wales in relapsed myeloma and trials of 'last line' therapy vs placebo cannot happen once there is phase 2 data: It would be useful to try and agree the following:-

- a set of criteria on when to give up Bortezomib in patients who are not showing sufficient response; and
- a decision not to use it again when patients progress.

Thank you for giving the Welsh Assembly Government the opportunity to comment on this appraisal.

Yours sincerely

A handwritten signature in black ink, appearing to be 'S. Owen', written over a faint dotted grid background.

Head of Healthcare Standards Branch  
HSC Quality, Standards and Safety Improvement Directorate