NICE requests more data on bortezomib for multiple myeloma

In draft guidance, published today (12 November), NICE has asked Janssen to provide more data on the effectiveness of their product, bortezomib (Velcade) as a treatment for some patients with newly diagnosed multiple myeloma.

This appraisal is examining the use of bortezomib for treating multiple myeloma in combination with dexamethasone and thalidomide. The draft guidance has been issued for consultation and the manufacturer now has an opportunity to respond to the independent Appraisal Committee's considerations and requests.

NICE has requested further evidence on the clinical and cost effectiveness of bortezomib in combination with dexamethasone compared with current standard treatment of newly diagnosed patients who are suitable for high dose chemotherapy with haematopoietic stem cell transplantation. Standard treatment in the UK is a combination of cyclophosphamide, thalidomide and dexamethasone.

The draft guidance does not currently recommend bortezomib in combination with thalidomide and dexamethasone.

Dr Carole Longson, Health Technology Evaluation Centre Director at NICE said: “The independent Appraisal Committee could not assess whether bortezomib in combination with dexamethasone is a cost-effective treatment option because it did not have sufficient information to do so. The next step in the NICE process is for the manufacturer to consider the Committee's comments and respond to its request for further evidence.”

Consultees, including the manufacturer, healthcare professionals and members of the public are now able to comment on the preliminary recommendations which are available for public consultation. Comments received during this consultation will be fully considered by the Committee and following this meeting the next draft guidance will be issued.

Until final guidance is issued, NHS bodies should make decisions locally on the funding of specific treatments. Once NICE issues its final guidance on a technology, it replaces local recommendations across the country.

Ends

Notes to Editors

About the guidance

1. The draft guidance will be available from 12 November 2013. Embargoed copies of the draft guidance are available from the NICE press office on request.

2. The cost of bortezomib is £762.38 per 3.5 mg vial. The average cost of a course of treatment with bortezomib given with dexamethasone is estimated to be £12,260.91 and the average cost of a course of treatment with bortezomib given with dexamethasone and thalidomide is estimated to be £24,840.10.

3. The Committee agreed that treatment with bortezomib and dexamethasone was associated with statistically significant improvements in post-induction overall response rates compared with vincristine, adriamycin and dexamethasone, whereas induction treatment with bortezomib, thalidomide and dexamethasone resulted in statistically significant improvements in overall response rates (post-induction and post-stem cell transplantation) and progression-free survival compared with thalidomide and dexamethasone. However, it concluded that no direct evidence was available to compare the efficacy of bortezomib, thalidomide and dexamethasone or bortezomib and dexamethasone with cyclophosphamide, thalidomide and dexamethasone, the comparator regimen considered to be current standard of care in the UK.

4. The most plausible cost per quality-adjusted life year (QALY) for bortezomib, thalidomide and dexamethasone compared with cyclophosphamide, thalidomide and dexamethasone was likely to be substantially higher than the £39,000 per QALY compared with thalidomide and dexamethasone.

5. NICE already recommends bortezomib as an option for the treatment of progressive multiple myeloma in people who are at first relapse having received one prior therapy and who have undergone, or are unsuitable for, bone marrow transplantation. NICE Technology Appraisal 129

6. Thalidomide in combination with an alkylating agent and a corticosteroid is recommended as an option for the first-line treatment of multiple myeloma in people for whom high-dose chemotherapy with stem cell transplantation is considered inappropriate. Bortezomib (Velcade, Janssen) is also recommended under these circumstances, if the person is unable to tolerate or has contraindications to thalidomide. NICE Technology Appraisal 228

7. Lenalidomide in combination with dexamethasone is recommended as a treatment option for people with multiple myeloma who have received two or more prior therapies.

About NICE

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Formerly the National Institute for Health and Clinical Excellence, our name changed on 1 April 2013 to reflect our new and additional responsibility to develop guidance and set quality standards for social care, as outlined in the Health and Social Care Act (2012).

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