

Summary of VELCADE® Response Scheme

Background

Velcade (Bortezomib) is slightly above NICE's usual £30k per QALY threshold. When used as monotherapy, Velcade has a cost per QALY of £33.5k. The company believes that when other additional relevant factors are considered (i.e. the innovative nature of the technology and the features of the condition and population receiving the technology) that this demonstrates sufficient cost effectiveness for positive NICE guidance. However, the company recognises the importance of ensuring patient access in the NHS and is, therefore, prepared to discuss an interim reimbursement scheme as a condition of positive NICE guidance in patients at 1st relapse. This scheme would further improve the cost effectiveness of Velcade monotherapy, allowing access to this important treatment, during which time the company will collect more cost-effectiveness data, ahead of another appraisal by NICE.

Voice of the Customer

The company has consulted with a number of Senior Haematologists and Pharmacists in England and Wales to seek feedback and ensure that the proposed scheme is both practical and workable in the NHS. We can confirm that the response of these stakeholders was positive towards such a scheme, which could be implemented with no incremental administrative cost to the NHS.

How the scheme could work

The NHS will fund patients at first relapse who achieve a response to Velcade and the company will provide replacement stock or credit for those patients at first relapse who fail to respond to Velcade. The scheme will be run on trust, although the company will request each participating hospital to sign a contract to access the scheme and reserve the right to audit anonymised patient-level data where higher than expected rebate patterns are observed. This is both to protect patient safety and to protect the company from fraudulent activities.

Definition of response and non-response to Velcade

It is routine in the treatment of Multiple Myeloma for clinicians to measure serum M-protein levels after each cycle of treatment. Response to Velcade can be defined as a patient achieving at least a Minimum Response (a 25% or greater reduction in serum M-protein) within the first 4 cycles of treatment. Non-response can be defined as having stable or progressive disease (i.e. less than a 25% improvement in serum M-protein) within the first 4 cycles of treatment.

Rebate levels and process

Given expected response rates, the company would expect to rebate at least 15% of the total cost of Velcade used in the NHS in England and Wales under this scheme. The company distributes Velcade directly to the NHS, so rebates or replacement stock can be given back to the same unit that placed the initial order, ensuring that the local health economy receives the benefit of the scheme.

Cost-effectiveness

Using a response scheme, with a 4-cycle stopping rule, the incremental cost per QALY for Velcade monotherapy is £30,800 (CI £27k - £39k), with a 71% probability of cost-effectiveness at a QALY of £35k.

Recommended Dosage and NHS cost

Velcade is available as a 3.5mg vial, with an NHS cost of £762.38/vial. The recommended starting dose is 1.3mg/m² body surface area (1 vial) twice weekly for two weeks, followed by a 10-day rest period. This 3 week period is a treatment cycle (4 vials). The cost of a treatment cycle is, therefore, £3,049. The maximum number of cycles is 8 (cost £24,396) and the average number of treatment cycles is 4.5 (cost £13,722)

Research Benefits of the Response Scheme

The direct distribution system in place would enable the company to collect national-level data on response rates in usual clinical practice. More importantly, the VRS, supported by positive NICE guidance would provide an opportunity for more detailed observational cost-effectiveness research to be undertaken in usual practice. The company would be prepared to share the level of rebate with the DH on an annual basis.