Scottish Medicines Consortium
Providing advice about the status of all newly licensed medicines
www.scottishmedicines.org.uk
Delta House 50 West Nile Street Glasgow G1 2NP Tel 0141 225 6999 Chairman: Professor Angela Timoney FRPharmS
NHS SCOTLAND

Product Update

bortezomib (Velcade®) 3.5mg powder for subcutaneous injection (No: 822/12)

Janssen-Cilag Ltd

09 November 2012

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and advises NHS Boards and Area Drug and Therapeutic Committees (ADTCs) on its use in NHS Scotland. The advice is summarised as follows:

ADVICE: following an abbreviated submission

bortezomib subcutaneous injection (Velcade®) is accepted for use within NHS Scotland.

Indications under review: in combination with melphalan and prednisone for the treatment of patients with previously untreated multiple myeloma who are not eligible for high-dose chemotherapy with bone marrow transplant.

As monotherapy for the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplantation.

The subcutaneous formulation of bortezomib has been shown to be clinically non-inferior to the intravenous formulation and is the same price.

SMC previously accepted bortezomib intravenous injection as monotherapy in the treatment of multiple myeloma when the benefits of a Patient Access Scheme (PAS) were taken into account. The Patient Access Scheme Assessment Group (PASAG) has confirmed that this response-based PAS also applies to the subcutaneous formulation when used in this setting. This SMC advice is therefore contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.

Bortezomib intravenous injection has also been accepted for use in NHS Scotland in specific circumstances in the first line treatment of multiple myeloma as Healthcare Improvement Scotland has endorsed NICE MTA No 228 (Bortezomib and thalidomide for the first line treatment of multiple myeloma) in July 2011. The PAS does not apply to the use of bortezomib in this setting.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after evaluation of the evidence submitted by the company. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

This assessment is based on data submitted by the applicant company up to and including 26 September 2012.

Chairman
Scottish Medicines Consortium