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March 2007 PBAC Outcomes – Subsequent Decision to Defer

Drug and Sponsor	Drug Use and Type	Listing requested by sponsor	PBAC Recommendation
Bortezomib, vial, 3.5 mg, (Velcade®) Janssen-Cilag Pty Ltd Minor submission	Anti cancer drug	Authority required listing for multiple myeloma after failure of thalidomide in certain patients who have progressive disease with a WHO performance status of 2 or less, who have received at least one prior therapy and who have already undergone or are ineligible for a primary stem cell transplant, and also in those who are unsuitable for thalidomide. Unsuitable for thalidomide treatment is defined according to the following contraindications in the TGA-approved Product Information: known hypersensitivity, pregnancy or breastfeeding, or inability to comply with adequate contraceptive measures in male and female patients of child-bearing age.	The PBAC decided to defer the submission to allow the sponsor to present a revised version of the modelled economic evaluation, which could be considered as a minor submission. The sensitivity of the economic model to cost offsets associated with the extent of substitution of HDT/SCT was pivotal to the PBAC's consideration. PBAC noted there is variation in clinical practice on the use of bortezomib and HDT/SCT and concluded that there is divergent clinical opinion on this matter. Thus, the extent of substitution remained unresolved.
		Sponsor's comment	In order to assist the PBAC in its consideration of bortezomib for PBS listing at its July 200 meeting, Janssen-Cilag has provided the additional requested sensitivity analyses.