

**MARCH 2011 PBAC MEETING OUTCOMES - Deferrals**

<b>DRUG AND FORM</b>	<b>DRUG USE AND TYPE</b>	<b>LISTING REQUESTED BY SPONSOR</b>	<b>PBAC OUTCOME AND COMMENTS</b>
<p>Bortezomib, powder for injection, 1 mg (solvent required), Velcade®</p> <p>Janssen – Cilag Pty Ltd</p> <p>Major submission</p>	<p>Multiple myeloma</p>	<p><u>Authority Required</u>                      Initial and continuing treatment as monotherapy or in combination with a corticosteroid and melphalan or cyclophosphamide in a patient with symptomatic multiple myeloma and severe renal impairment (GFR ≤ 30, after adequate hydration) who                      (1) is newly diagnosed and receiving bortezomib as front line therapy, or                      (2) who commenced treatment on thalidomide with a resultant GFR drop to ≤ 30.</p>	<p>The PBAC deferred the submission to enable discussion with clinicians and the sponsor regarding eligibility criteria for first-line use in a patient with acute renal failure whose GFR is falling and where a renal physician would consider the patient at risk of requiring dialysis, so that those with the greatest clinical need will have access to PBS-subsidised bortezomib.</p>
		<p>Sponsor's comments:</p>	<p>The sponsor has no comment.</p>