

DECEMBER 2017 PBAC OUTCOMES – DEFERRALS

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>EVEROLIMUS</p> <p>Tablet, dispersible, 2 mg Tablet, dispersible, 3 mg Tablet, dispersible, 5 mg</p> <p>Afinitor®</p> <p>Novartis Pharmaceuticals Australia</p>	<p>Tuberous sclerosis complex</p>	<p>To request an Authority Required listing for the treatment of patients with refractory seizures associated with tuberous sclerosis complex in combination with other anti-epileptic medications.</p>	<p>The PBAC deferred its decision about whether to extend the listing of everolimus to include the treatment of refractory seizures associated with tuberous sclerosis complex (TSC). In deciding to defer, the PBAC acknowledged the unmet clinical need in this patient population, and the likelihood that everolimus would provide an important benefit in at least some patients, but did not consider that the current submission provided an appropriate basis to support a listing. The PBAC therefore requested that the Department work with the sponsor on the proposed restriction, price, and estimation of financial impact.</p>
		<p align="center">Sponsor Comment:</p>	<p>The Sponsor is working with the Department to make everolimus available for this rare condition</p>
<p>ROMIDEPSIN</p> <p>Powder for I.V. infusion 10 mg</p> <p>Istodax®</p> <p>Celgene Pty Ltd</p>	<p>Relapsed or refractory peripheral T-Cell lymphoma (PTCL)</p>	<p>Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of relapsed or refractory PTCL.</p>	<p>The PBAC deferred its decision about whether to recommend the listing romidepsin for the treatment of peripheral T-cell lymphoma. The PBAC accepted that romidepsin provided a degree of clinical benefit in some patients. However, the PBAC considered that the most appropriate comparison was against pralatrexate, which has been recommended for PBS listing in this population. Consequently the PBAC deferred its decision to allow for further discussion with the sponsor around a comparison against pralatrexate ahead of further consideration by the PBAC.</p> <p>In making this decision, the PBAC recognised the high and unmet clinical need for an additional or alternative effective therapy in a group of patients with advanced peripheral T-cell lymphoma after the failure of prior systemic therapy.</p>
		<p align="center">Sponsor Comment:</p>	<p>The sponsor will continue to work with the PBAC with the view to PBS listing of Romidepsin for PTCL patients in Australia.</p>