

JULY 2016 PBAC MEETING – DEFERRALS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>DACLIZUMAB</p> <p>150 mg/mL solution for injection, 1 mL pen-filled pen 150 mg/mL solution for injection, 1 mL syringe</p> <p>Zinbryta®</p> <p>Biogen Australia Pty Ltd</p> <p>New listing</p> <p>(Major Submission)</p>	<p>Relapsing-remitting multiple sclerosis</p>	<p>Authority Required listing for the treatment of relapsing-remitting multiple sclerosis.</p>	<p>The PBAC deferred making a recommendation on the listing of daclizumab, on the basis that the clinical place for which TGA registration may be approved was unclear and that this would have a significant impact on the choice of comparator for any cost minimisation analysis and the wording of any possible restriction. The PBAC considered that fingolimod was not an appropriate sole comparator for daclizumab and that the choice of comparator may be aided by the clinical place as described in the TGA registration but, may include dimethyl fumarate and possibly other injectable therapies for MS.</p>
		<p>Sponsor comment:</p>	<p>Biogen looks forward to working with the Department to make daclizumab available to patients for the treatment of relapsing-remitting multiple sclerosis.</p>
<p>EMTRICITABINE with RILPIVIRINE and TENOFOVIR</p> <p>emtricitabine 200 mg + rilpivirine 25 mg + tenofovir alafenamide 25 mg tablet, 30</p> <p>Odefsey®</p> <p>Gilead Sciences Pty Ltd</p>	<p>Human immunodeficiency virus (HIV)</p>	<p>Authority Required (STREAMLINED) listing for treatment of HIV infection.</p>	<p>The PBAC deferred making a recommendation on whether tenofovir alafenamide with emtricitabine and rilpivirine should be listed on the PBS for the treatment of HIV infection.</p> <p>The PBAC formed the view that Odefsey® (rilpivirine 25 mg + emtricitabine 200 mg + tenofovir alafenamide 25 mg tablet) is non inferior to Eviplera® (tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + rilpivirine 25 mg tablet) in terms of effectiveness and safety. The equi-effective doses are one tablet of Odefsey is equivalent to one tablet of Eviplera.</p>

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<p>New listing (Major Submission)</p>		<p align="center">Sponsor comment:</p>	<p>The sponsor had no comment.</p>
<p>SACUBITRIL with VALSARTAN</p> <p>sacubitril 24 mg + valsartan 26 mg tablet, 56 sacubitril 49 mg + valsartan 51 mg, tablet, 56 sacubitril 97 mg + valsartan 103 mg, tablet, 56</p> <p>Entresto®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>New listing (Minor Submission)</p>	<p>Chronic heart failure</p>	<p>Resubmission for Authority Required (STREAMLINED) listing for the treatment of chronic heart failure with reduced ejection fraction.</p>	<p>The PBAC deferred making a recommendation on whether sacubitril with valsartan should be listed on the PBS for the treatment of patients with chronic heart failure and a reduced left ventricular ejection fraction, pending further price negotiations with the sponsor. The PBAC noted the price reduction of sacubitril with valsartan in the resubmission compared to the requested price in March 2016, but considered that this price reduction was not sufficient to account for the uncertainties surrounding cost effectiveness.</p> <p>The clinical evidence and structure of the economic model remained unchanged from the March 2016 major submission. The PBAC recalled that it considered the clinical claim of superior comparative effectiveness compared to enalapril was reasonable, but that size of the benefit remained uncertain due to the issues with study design and early stopping of the PARADIGM-HF trial. The PBAC considered that the claim of non-inferior comparative safety to enalapril was reasonable. The PBAC recalled that it was previously concerned that the model did not accurately reflect the disease progression of patients with heart failure and the baseline heart failure mortality was not reflective of that for the likely PBS</p>

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			<p>population.</p> <p>The PBAC noted the financial impact of listing sacubitril with valsartan was high and there would be a significant opportunity cost to the Commonwealth. The PBAC considered that the high predicted financial impact of listing was of particular concern in the context of the magnitude of clinical benefit and the cost-effectiveness of treatment being unknown.</p>
<p>TENOFOVIR with EMTRICITABINE</p> <p>tenofovir alafenamide 10 mg + emtricitabine 200 mg tablet, 30</p> <p>tenofovir alafenamide 25 mg + emtricitabine 200 mg tablet, 30</p> <p>Descovy®</p> <p>Gilead Sciences Pty Ltd</p> <p>New listing</p>	<p>Human immunodeficiency virus (HIV)</p>	<p>Authority Required (STREAMLINED) listing for treatment of HIV infection.</p>	<p>The PBAC deferred making a recommendation on whether tenofovir alafenamide with emtricitabine should be listed on the PBS for the treatment of HIV infection.</p> <p>The PBAC formed the view that Descovy® (emtricitabine 200 mg + tenofovir alafenamide 10 mg or 25 mg tablet) is non inferior to Truvada® (tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet) in terms of effectiveness and safety. The equi-effective doses are:</p> <ul style="list-style-type: none"> • Descovy (emtricitabine 200 mg / tenofovir alafenamide 10 mg) in a pharmacokinetic boosted regimen; • Descovy (emtricitabine 200 mg / tenofovir alafenamide 25 mg) in an un-boosted pharmacokinetic regimen; with • Truvada (emtricitabine 200 mg / tenofovir disoproxil fumarate 300 mg), regardless of boosted or unboosted pharmacokinetic regimen.

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(Major Submission)			
<p>WHEY PROTEIN FORMULA with MEDIUM CHAIN TRIGLYCERIDES, CARBOHYDRATE, VITAMINS and MINERALS</p> <p>Oral liquid, 24 × 200 mL bottles,</p> <p>Infatrini Peptisorb[®]</p> <p>Nutricia Australia Pty Ltd</p>	<p>Dietary management of conditions requiring a source of medium chain triglycerides</p>	<p>Restricted benefit listing for the dietary management of infants with gastrointestinal malabsorption or maldigestion requiring a source of medium chain triglycerides.</p>	<p>The PBAC deferred making a recommendation on the PBS listing of Infatrini Peptisorb[®] as a Restricted Benefit for the dietary management of conditions requiring a source of medium chain triglycerides. The PBAC considered that the main comparator was unsuitable due to the discrepancies in nutritional composition to Monogen[®].</p>
		<p align="center">Sponsor comment:</p>	<p>The sponsor had no comment.</p>