

AUGUST 2016 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>IDELALISIB</p> <p>100 mg tablet, 60 150 mg tablet, 60</p> <p>Zydelig®</p> <p>Gilead Sciences Pty Ltd</p> <p>Matters Outstanding</p> <p>(Minor Submission)</p>	<p>Chronic lymphocytic leukaemia and small lymphocytic lymphoma</p>	<p>To seek PBAC's advice on which molecular markers should be included in the PBS restriction for idelalisib for the treatment of chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL).</p>	<p>The PBAC recommended the PBS restriction for idelalisib for relapsed/refractory chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) include the requirement for patients to have evidence of a 17p deletion (noting that this test is yet to be considered by the Medical Services Advisory Committee). The PBAC also recommended including the TP53 mutation requirement for patients testing negative for the 17p deletion, if a test for TP53 mutation is made available through the Medicare Benefits Schedule.</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 Limited</p> <p>New Listing</p> <p>(Minor Submission)</p>	<p>Chronic Heart Failure</p>	<p>Authority Required (STREAMLINED) listing for the treatment of chronic heart failure with reduced ejection fraction.</p>	<p>The PBAC recommended the listing of sacubitril with valsartan for the treatment of patients with chronic heart failure and a reduced left ventricular ejection fraction on the basis of acceptable cost effectiveness compared to enalapril. The PBAC noted the reduced price proposed, the revised PBS expenditure estimates and considered the proposed two-tier capping levels to be a reasonable basis for the Risk Sharing Arrangement.</p>
<p>QUADRIVALENT INFLUENZA VACCINE</p> <p>Pre-filled syringe, 0.5 mL</p> <p>Afluria® Quad</p>	<p>Prevention of seasonal Influenza</p>	<p>Listing on the National Immunisation Program (NIP) – Designated Vaccines list for the prevention of seasonal influenza</p>	<p>The PBAC deferred making a decision on the listing of Afluria® Quad on the NIP at the August 2016 PBAC meeting.</p> <p>Subsequent to the August 2016 meeting, the PBAC recommended the listing of Afluria® Quad on the NIP – Designated Vaccines List for the prevention of seasonal</p>

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Seqirus Australia (Major Submission)			influenza for adults aged 18 years and older who are eligible to receive NIP-funded influenza vaccine. The recommendation was made on a cost minimisation basis with Fluarix [®] Tetra influenza vaccine, with the equi-effective doses being one dose of 0.5 mL Afluria [®] Quad and one dose of 0.5 mL Fluarix [®] Tetra.