MAY 2019 PBAC MEETING – POSITIVE RECOMMENDATIONS

SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
BENZATHINE BENZYLPENICILLIN Injection, 1.2 million units (900 mg)/2.3 mL 10 x 2.3 mL syringes Bicllin L-A® Pfizer Australia Pty Ltd Change to listing (Minor Submission)	Antibacterial	The submission requested a listing for benzathine benzylpenicillin (Bicillin L-A) on the Emergency Drug Supply (EDS) list. The listing is intended to provide treatment for syphilis in Aboriginal and Torres Strait Islander patients in non-remote areas.	The PBAC recommended the listing of benzathine benzlypenicillin (Bicillin L-A) on the Emergency Drug Supply Schedule (Prescribers Bag). The listing is intended to provide treatment for syphilis in Aboriginal and Torres Strait Islander patients in non-remote areas.
BEVACIZUMAB Solution for intravenous infusion 100 mg in 4 mL 400 mg in 16 mL Avastin®, Roche Products Pty Limited Change to listing (Minor Submission)	Relapsed or refractory glioblastoma.	The resubmission requested the Section 100 (Efficient Funding of Chemotherapy), Authority Required listing of bevacizumab for the treatment of relapsed or refractory glioblastoma.	The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy) Authority Required listing of bevacizumab for the treatment of relapsed or refractory glioblastoma. The PBAC considered there is a high unmet clinical need for treatments for patients with relapsed or refractory glioblastoma, and acknowledged the large number of comments from consumers, clinicians and organisations received for the March 2019 meeting. The PBAC considered that bevacizumab was associated with improvements in response rates and progression free survival, and hence quality of life through control over deterioration and symptom management. While the PBAC considered that there remained uncertainty in the magnitude of some of these benefits, the PBAC noted that the benefits, as described by consumers and clinicians included: improved neurological function, improved mobility, and a reduction in steroid dose and a restoration of dignity. The PBAC also noted that across studies, the objective response rate with bevacizumab was between 30% and 40%. Overall, the PBAC was satisfied that bevacizumab provides, for some patients, an improvement in efficacy over standard care (salvage chemotherapy).

SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
Biologics for the treatment of severe asthma BENRALIZUMAB Injection 30 mg in 1 mL (prefilled syringe) Fasenra® AstraZeneca Pty Ltd MEPOLIZUMAB Injection 100 mg, 1 vial Nucala® GlaxoSmithKline Australia Pty Ltd OMALIZUMAB Injection 75 mg/0.5 mL syringe 150 mg/mL syringe Xolair® Novartis Pharmaceuticals Australia Pty Limited	Severe asthma	To provide advice on the proposed PBS restriction changes to biologic medicines for severe asthma.	The PBAC recommended several changes to the current PBS restrictions for biologic medicines for severe asthma. These changes were informed by the outcomes of the December 2018 asthma stakeholder meeting. The recommended changes are as follows: Initial treatment: • Amendment of the eosinophil cut-off from ≥ 300 cells per µL to 150 cells per µL for patients on oral corticosteroids • Removal of the forced expiratory volume (FEV1) ≤ 80% predicated normal • For omalizumab only, removal of the requirement for RAST testing and replacement with “Past or present evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE” • A 32 week initial treatment period across all three medicines. Continuing treatment: • Continuation of therapy where Asthma Control Questionnaire (ACQ) is no greater than 0.5 higher than baseline where oral corticosteroid (OCS) dose has been reduced. Switching: • A new ‘initial 2’ restriction for patients switching therapy to remove the current requirement for a 6 month break between treatments. Re-trialling and cycling: • Re-trial of the same biologic after previous failure following a 12 month break (increased from the current 6 month break).

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BLINATUMOMAB Powder for I.V. infusion 38.5 micrograms Blincyto® Amgen Australia Pty Limited INOTUZUMAB OZOGAMICIN Powder for I.V. infusion 1 mg Besponsa® Pfizer Australia Pty Ltd Change to listing (Minor submission)	Acute lymphoblastic leukaemia (ALL)	The extension of the recommended listing of inotuzumab ozogamicin and blinatumomab for the treatment of relapsed or refractory (R/R) Philadelphia chromosome negative (Ph-) CD22 positive B-cell precursor acute lymphocytic leukaemia (B-ALL) to include patients with R/R Philadelphia chromosome positive (Ph+) B-ALL.	The PBAC recommended extending the listings of blinatumomab and inotuzumab to include patients with Ph+ disease on the basis that it considered blinatumomab and inotuzumab would be sufficiently effective and cost-effective in patients with Ph+ disease. The PBAC reaffirmed there is a high clinical need in patients with Ph+ disease (R/R B-ALL) particularly given it is generally associated with a poorer prognosis than Ph- disease. The PBAC considered the treatment effect was unlikely to differ significantly based on Philadelphia chromosome status and was therefore satisfied that blinatumomab and inotuzumab would be sufficiently cost-effective in Ph+ disease. The PBAC considered the financial impact of amending the restrictions for both drugs would be relatively small compared to the Ph- population.

MAY 2019 PBAC MEETING – POSITIVE RECOMMENDATIONS

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MENINGOCOCCAL VACCINE (conjugate ACWY) 13-VALENT PNEUMOCOCCAL CONJUGATE VACCINE (13vPCV) 23-VALENT PNEUMOCOCCAL POLYSACCHARIDE VACCINE (23vPPV) HAEMOPHILUS INFLUENZAE TYPE B VACCINE (Conjugate Hib) (all NIP listed brands)	Meningococcal, pneumococcal and Haemophilus influenzae type b disease	To extend the circumstances in which recommended vaccines are available on the National Immunisation Program (NIP) for people with asplenia and hyposplenia.	The PBAC recommended that the following vaccinations be listed on the NIP schedule for patients with asplenia and hyposplenia – Meningococcal serogroups A, C, W135 and Y vaccine (Men ACWY), 13-valent pneumococcal conjugate vaccine (13vPCV), 23-valent pneumococcal polysaccharide vaccine (23vPPV) and Haemophilus influenzae type b (Conjugate Hib). The PBAC noted that influenza vaccination is already available on the NIP for all patients with asplenia and hyposplenia. The PBAC considered that the populations with asplenia and hyposplenia had a high clinical need for these vaccines, and that the vaccines would be as cost-effective in this population as in the current NIP subsidised populations. The PBAC noted that the vaccination schedule for patients with asplenia and hyposplenia in the Australian Immunisation Handbook was recommended by ATAGI, and considered that access to the vaccines mentioned above to this population through the NIP was appropriate.
MENINGOCOCCAL VACCINE (conjugate ACWY) (all NIP listed brands)	Meningococcal disease	To extend the circumstances in which meningococcal ACWY vaccine is a designated vaccines on the National Immunisation Program (NIP) to include people with complement deficiencies or undergoing eculizumab treatment.	The PBAC recommended that the Meningococcal serogroups A, C, W135 and Y vaccine (Men ACWY) should be added to the NIP schedule for people with complement deficiency and for patients undergoing treatment with eculizumab. The PBAC considered that people with complement deficiency and those treated with eculizumab had a high clinical need for vaccination, and that the vaccine would be as cost-effective in this population as in the current NIP listed population.