DECEMBER 2017 PBAC MEETING – POSITIVE RECOMMENDATIONS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
ADALIMUMAB Injection 40 mg in 0.4 mL pre-filled syringe Injection 40 mg in 0.4 mL pre-filled pen Humira® AbbVie Pty Ltd	All current subsidised indications of adalimumab on the PBS	To request Authority Required listings for an alternative formulation of adalimumab, for all existing PBS subsidised indications.	The PBAC recommended the Authority Required listing of adalimumab 40 mg/0.4mL formulation, with the same restrictions as the currently listed 40 mg/0.8mL form of adalimumab. In making this recommendation, the PBAC noted that although the application for the 40 mg/0.4 mL formulation met the requirements for a positive PBAC recommendation, the evidence that there is a clinical need for a new formulation was not convincing.
CABOZANTINIB Tablet 20 mg Cabometyx® Ipsen Pty Ltd	Clear cell variant renal cell carcinoma (RCC)	To request an Authority Required (STREAMLINED) listing for the treatment of Stage IV clear cell variant RCC in patients previously treated with a tyrosine kinase inhibitor (TKI).	The PBAC recommended listing cabozantinib for the treatment of Stage IV clear cell variant renal cell carcinoma, on a cost-minimisation basis against nivolumab. The PBAC considered that cabozantinib had non-inferior efficacy compared to nivolumab and whilst there was possibly increased toxicity associated, this was manageable and balanced against a clinical need for an alternative to immunotherapy in this patient population.
FLUTICASONE FUROATE WITH UMECLIDINIUM AND VILANTEROL Powder for oral inhalation in breath actuated device containing fluticasone furoate 100 micrograms with umeclidinium 62.5 micrograms (as bromide) and vilanterol 25 micrograms (as trifenatate) per dose Trelegy® Ellipta® GlaxoSmithKline Australia Pty Ltd	Chronic obstructive pulmonary disease (COPD)	To request an Authority Required (STREAMLINED) listing for the treatment of patients with moderate to severe COPD (FEV<50% predicted) and frequent exacerbations despite regular maintenance treatment.	The PBAC recommended an Authority Required (Streamlined) listing of fluticasone furoate with umeclidinium and vilanterol (Trelegy), a triple therapy inhaler containing long-acting muscarinic antagonist (LAMA), long-acting beta2 agonist (LABA) and inhaled corticosteroid (ICS), for the treatment of Chronic Obstructive Pulmonary Disease (COPD). The PBAC considered that, based on the evidence presented in the submission, there could be a modest benefit of triple therapy over LAMA/LABA dual therapy in some patients, but this was balanced against expected increased harms associated with more prolonged ICS use. The PBAC advised that Trelegy would be acceptably cost-effective if its price was not substantially greater than the price of LAMA/LABA dual therapy. The PBAC considered that there was a risk of inappropriate use earlier in the treatment pathway than clinically necessary or in patients with asthma. This inappropriate use may grow the triple therapy market, and PBAC therefore advised that a risk sharing arrangement would be appropriate to contain total cost.

TENOFOVIR with EMTRICITABINE Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg Truvada® Gilead Sciences Pty Limited Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg Tenofovir Disoproxil Emtricitabine Mylan 300/200® Alphapharm Pty Ltd. (trading as Mylan) Tablet containing tenofovir disoproxil phosphate 291 mg with emtricitabine 200 mg Tenofovir EMT GH® Generic Health Pty Ltd.	Human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP)	To provide the PBAC with additional economic analyses and utilisation scenarios prepared by the Kirby Institute, as requested by the PBAC when it deferred the requests for the following applications at its July 2017 meeting: Resubmission to request an Authority Required (STREAMLINED) listing for PrEP in adults at medium to high risk of HIV infection. (Gilead Sciences Pty Limited) To request an Authority Required (STREAMLINED) listing for PrEP in adults at high risk of HIV infection. (Alphapharm Pty Ltd. trading as Mylan) To request an Authority Required (STREAMLINED) listing for PrEP in adults at high risk of HIV infection. (Generic Health Pty Ltd)	The PBAC recommended the listing of tenofovir with emtricitabine for human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP) in certain patients at medium to high risk of HIV infection. The PBAC was satisfied that tenofovir with emtricitabine provides, for some patients, a significant reduction in the risk of sexually-acquired HIV, in combination with other safe sex practices, compared with safe sex practices alone. The PBAC's recommendation for listing was based on, among other matters, its assessment of the cost-effectiveness of PrEP based on the model developed by the Kirby Institute. The PBAC reaffirmed its position that it was appropriate for an eligible population to include medium and high risk individuals as defined in the PrEP guidelines published by the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM), and that patients should return a negative HIV test result prior to commencing PrEP. The Committee emphasised that tenofovir with emtricitabine as PrEP should form part of a comprehensive approach to sexual health and complement other safe sex practices, including condom use. The PBAC noted the cost-effectiveness of PrEP was dependent on the extent of uptake and the risk profile of the individuals in which PrEP is utilised, and considered the impact of a number of uptake scenarios on the cost-effectiveness of PrEP. Overall, the PBAC advised that tenofovir with emtricitabine for PrEP would be acceptably cost-effective if the annual treatment cost was no more than $2,500 per patient.
BRENTUXIMAB VEDOTIN 50 mg powder for injection Adcetris® Takeda Pharmaceuticals Australia Pty Ltd.	CD30 positive systemic anaplastic large cell lymphoma (sALCL)	To request the removal of the requirement for an additional biopsy from the brentuximab vedotin restriction for the treatment of CD30+ sALCL.	The PBAC recommended the removal of the phrase relating to the timing of the biopsy subsequent to the most recently delivered prior treatment with radiation, chemotherapy, biologics, immunotherapy or other agents' from the brentuximab vedotin initial treatment restriction for CD30 positive systemic anaplastic large cell lymphoma. In making its decision, the PBAC considered that this criterion was no longer required as CD30+ status is typically constant over the course of the disease, and that patients would benefit if a repeat biopsy was not clinically indicated.

Other business Australian Technical Advisory Group on Immunisation (ATAGI) review on pertussis vaccinations	National Immunisation Program (NIP) listed pertussis vaccinations	The PBAC considered additional advice provided by ATAGI in response to PBAC's July 2017 consideration of the review of pertussis vaccinations	The Committee accepted the ATAGI's advice that even with the inclusion of pertussis vaccination of women during each pregnancy, which it had recommended at its July 2016 meeting, removing any existing pertussis vaccine dose from the current NIP schedule could be expected to result in an increased incidence of pertussis infections, and a corresponding reduction in herd immunity. Accordingly the PBAC recommended that a review of the cost-effectiveness of the pertussis vaccinations currently listed on the NIP schedule was not warranted at this time. The PBAC recalled that its July 2016 recommendation to change the circumstances under which the pertussis vaccination is made available as a designated vaccine on the NIP, to include vaccination of women during each pregnancy, was made on the basis of cost-effectiveness compared with no vaccination. The Committee noted that this addition to the NIP schedule for the pertussis vaccinations has not yet occurred.