JULY 2019 PBAC OUTCOMES – OTHER MATTERS

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
Cost-effectiveness review of pneumococcal vaccines for the National Immunisation Program (NIP). Pneumovax 23® Seqirus Australia Pty Ltd Prevenar 13® Pfizer Australia Pty Ltd Australian Technical Advisory Group on Immunisation (ATAGI)	Vaccines for the prevention of pneumococcal disease	To consider the eligible populations for vaccination with a 23-valent pneumococcal polysaccharide vaccine (23vPPV) or a 13-valent pneumococcal conjugate vaccine (13vPCV) via the National Immunisation Program (NIP).	In July 2016, the PBAC recommended Prevenar 13® (13vPCV) to replace the first dose of Pneumovax 23® (23vPPV) for older adults based on cost effectiveness over the 23vPPV. At that time, the PBAC noted that the cost-effectiveness of 23vPPV had not been previously reviewed, and requested advice from the ATAGI on the clinical place and effectiveness of 23vPPV on the NIP, with a view to potentially informing a review of the cost-effectiveness of 23vPPV. The PBAC noted that any outcomes of the review of 23vPPV might have implications for the 13vPCV listing. In July 2017, the PBAC considered the advice of the ATAGI and recommended a cost effectiveness review (CER) of 23vPPV compared with no vaccine in the current NIP-funded indications for: • Non-Aboriginal and Torres Strait Islander adults aged ≥65 years, with and without risk factors; and • Aboriginal and Torres Strait Islander adults aged ≥50 years, with and without risk factors. Given the high and disproportionate burden of invasive pneumococcal disease in Aboriginal and Torres Strait Islander adults, the PBAC also recommended a review of a stepped economic analysis and financial impact of providing 13vPCV, with or without 1 or 2 doses of 23vPPV, to Aboriginal and Torres Strait Islander people ≥50yrs not previously vaccinated with a 7-valent pneumococcal conjugate vaccine or 13vPCV. The PBAC first considered the CER report in December 2018 and sought further advice from the ATAGI on a proposed pneumococcal NIP schedule for individuals aged 12 months and older at high-risk of pneumococcal disease, where use of 13vPCV and 23vPPV could be considered cost-effective. At its March 2019 meeting, the PBAC considered updated ATAGI advice. The PBAC accepted ATAGI's advice and considered it would be appropriate to fund one dose of 13vPCV and two doses of 23vPPV for those aged 12-59 months with the at-risk conditions ATAGI had identified (which included patients with asplenia, immunocompromised conditions, chronic respiratory or renal disease, cerebrospinal fluid leak, cochlear

			implants, intracranial shunts or previous episodes of invasive pneumococcal disease). The PBAC also revisited its consideration of the CER and affirmed the findings, which supported routine vaccination with 13vPCV in older, healthy adults ≥75 years, based on acceptable cost-effectiveness. The PBAC also affirmed its view that one dose of the 13vPCV and two subsequent doses of the 23vPPV in the Aboriginal and Torres Strait Islander population ≥50 years could be included on the NIP, based on high but acceptable cost-effectiveness in this population. In July 2019, the PBAC considered further ATAGI advice on an enhanced pneumococcal immunisation schedule addressing both age based and at-risk eligible populations and the feedback from stakeholders including sponsors, clinicians and consumer groups. The PBAC noted the ATAGI advice and agreed to their further advice to revise the age of vaccination for non- Aboriginal and Torres Strait Islander adults with 13vPCV from ≥75 to ≥70 years to align the vaccination age with the Zostavax schedule, and to facilitate the implementation and uptake of the pneumococcal program. The PBAC therefore recommended the following pneumococcal vaccine schedule, including both the 13vPCV and 23vPPV as having acceptable cost-effectiveness for inclusion on the NIP for the following: • All healthy non-Aboriginal and Torres Strait Islander adults ≥ 70 years: 13vPCV (single dose); • All Aboriginal and Torres Strait Islander adults ≥50 years: 13vPCV (single dose) and 23vPPV (two subsequent doses approximately five years apart); • In all persons ≥5 years newly diagnosed with a condition putting them at very high risk of pneumococcal infection: 13vPCV (single dose) and 23vPPV (two subsequent doses approximately five years apart). Based on ATAGI advice on the high pneumococcal disease rates in certain high risk infant populations, the following additions were also recommended to the infant pneumococcal program for children under five years of age: • Non-Aboriginal and Torres Strait Islander children 2-12 months with very high risk of pneumococcal infection: an additional dose of 13vPCV (single dose) at 6 months (already funded for Aboriginal and Torres Strait Islander children at 6 months) and 23vPPV (two subsequent doses approximately five years apart)

			• Aboriginal and Torres Strait Islander children <5 years living in Western Australia, Queensland, South Australia and Northern Territory (areas of high incidence): Two additional doses of 23vPPV following the currently funded additional dose of 13vPCV at 6 months • Children 12-59 months newly diagnosed with a condition putting them at very high risk of pneumococcal infection: 13vPCV (single dose) and 23vPPV (two subsequent doses approximately 5 years apart) The revised pneumococcal vaccination schedule will ensure that all very high-risk populations are eligible for vaccination with both the 13vPCV and the 23vPPV on the NIP. Therefore, the PBAC considered the PBS listing for 23vPPV for those at high risk of pneumococcal infection was no longer required and recommended delisting the vaccine from the PBS.
Asthma - terbutaline on the PBS	Terbutaline	The PBAC was asked to advise whether terbutaline inhalation should be retained on the PBS on the basis of clinical need, or whether available forms of salbutamol for oral inhalation are suitable alternatives.	The PBAC recommended that terbutaline powder for oral inhalation be retained on the PBS to address an unmet clinical need for patients who are unable to use short-acting beta-2 agonist pressurised metered dose inhalers (pMDI) for the treatment of bronchospasm. The PBAC recommended that the current unrestricted benefit listing of terbutaline powder for oral inhalation be amended to an Authority Required (STREAMLINED) listing and that the clinical criteria should restrict use to patients unable to use a pMDI, or patients who suffer from adverse effects with the use of salbutamol, including patients who experience paradoxical bronchoconstriction with pMDI.