AUGUST 2019 PBAC MEETING – OTHER MATTERS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
Antibiotic repeats on the Pharmaceutical Benefits Scheme (PBS) Various Medicines Various Brands Various Sponsors	Various infections	For the PBAC to consider changes to the listing of certain antibiotics to encourage antimicrobial stewardship.	Following a review conducted by the Department of Health, the PBAC recommended changes to antibiotic listings for high use items on the PBS with repeat prescription options. The PBAC recommended the removal of repeat options for a range of listings where no repeats were deemed necessary as per the Therapeutic Guidelines. The PBAC also recommended aligning the listings for specific indications to the Therapeutic Guidelines where increased quantities are clinically indicated. The PBAC considered that the recommended changes, aligned as best possible with the current version of the Therapeutic Guidelines (version 16), would support antimicrobial stewardship and quality use of medicines as well as assist in the reduction of antimicrobial resistance.
Broad PBS subsidy listing for PD-(L)1 checkpoint inhibitors for non-small cell lung cancer (NSCLC) Various Medicines Various Brands Various Sponsors	Non-small cell lung cancer (NSCLC)	For the PBAC to consider four proposals for a broad subsidy of PD-(L)1 inhibitors in NSCLC following a stakeholder meeting in February 2019.	The PBAC considered four proposals received from: • AstraZeneca Pty Ltd for durvalumab (ImfinziTM), • Bristol-Myers Squibb Australia Pty Ltd for nivolumab (Opdivo®), • Merck Sharp & Dohme (Australia) Pty Ltd for pembrolizumab (Keytruda®), and • Roche Products Pty Ltd for atezolizumab (Tecentriq®). The PBAC decided not to recommend a broad stage III / stage IV NSCLC listing that would encompass all four drugs at this time. However, the PBAC decided to recommend that pembrolizumab (Keytruda) be listed for 1st line use in combination with chemotherapy, for previously untreated Stage IV, squamous EGFR/ALK/ROS1 wild-type NSCLC. The PBAC noted that this is the only group of patients with NSCLC for whom a first line PD-(L)1 PBS listing is not currently available.

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PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® Merck Sharp & Dohme (Australia) Pty Ltd	Non-small cell lung cancer (NSCLC)	To seek the PBAC's advice about the future place of first line pembrolizumab monotherapy for NSCLC following the PBAC's July 2019 recommendation for pembrolizumab in combination with platinum chemotherapy and pemetrexed for the first-line treatment of Stage IV NSCLC.	The PBAC considered options to re-establish certainty of the cost-effectiveness of existing PBS-listed pembrolizumab monotherapy for patients with previously untreated Stage IV non-small cell lung cancer (NCSLC) whose tumours express programmed death-ligand 1 (PD-L1) at tumour proportion score (TPS) ≥ 50%. The PBAC recalled that, in the absence of the price reduction recommended at its March 2019 meeting, it had advised it would re-consider the future place of pembrolizumab monotherapy for NSCLC if an alternative first-line immunotherapy regimen became available on the PBS. Potential options would include limiting access of pembrolizumab subsidy to only include patients for whom no other first-line immunotherapy based option for NSCLC is available on the PBS. The PBAC noted that the July 2019 recommendation to list pembrolizumab in combination with platinum chemotherapy and pemetrexed for the treatment of patients with Stage IV non-squamous NSCLC would provide an alternative first-line immunotherapy regimen. The PBAC disagreed with the sponsor's argument that the long-term KEYNOTE 001 trial data supported the current pembrolizumab monotherapy vial price. The PBAC considered the treatment naïve dataset with a TPS ≥50% in this phase I study was too small to allow meaningful comparisons to be made with the data from the larger phase III KEYNOTE 24 and KEYNOTE 042 studies. The PBAC considered that if a revised price from the sponsor was not forthcoming, there was no clinical reason the Minister (Delegate) should not amend the circumstances for pembrolizumab to restrict pembrolizumab monotherapy to patients for whom no other first-line immunotherapy option is available (i.e. patients with previously untreated Stage IV squamous cell NSCLC whose tumours express PD-L1 at TPS ≥ 50% and who are epidermal growth factor receptor (EGFR) wild type and anaplastic lymphoma kinase (ALK) negative).

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Pulmonary arterial hypertension (PAH) hospital application process	Agents for the treatment of pulmonary arterial hypertension (PAH)	To note the outcome of the Department's review of the guidelines for PAH designated prescribing centres in regard to specific recommendations on patient numbers and available clinical expertise and resulting change in administration processes	The PBAC noted the Department of Health will cease the administrative hospital approval process to access PAH medicines and acknowledged that administrative arrangements to determine a PAH designated hospital are not equivalent to the establishment of centres of excellence for the management of PAH. Given the complexity of the condition, the PBAC noted the concerns raised by stakeholders regarding the ongoing safety and appropriate clinical management of patients with PAH without the establishment of centres of excellence. The PBAC recognised the vital role that centres of excellence or referral centres should play in the diagnosis and management of complex health conditions such as PAH, but noted that arrangements for the establishment and maintenance of such centres is beyond the remit of the PBAC. The PBAC considered that discussions about the arrangements for PAH centres of excellence should occur with State and Territory Health Departments and the relevant peak professional bodies.

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RISPERIDONE 500 microgram tablet, 20, 60 1 mg tablet, 60 1 mg / mL oral liquid, 100 mL Various Brands Various Sponsors	Behavioural and psychological symptoms of dementia (BPSD)	To seek advice about amending the current listing and establishing an additional authority code to reduce inappropriate use of risperidone to treat BPSD.	In the context of addressing issues of inappropriate prescribing of chemical restraints to control behavioural and psychological symptoms of dementia (BPSD), the PBAC agreed and recommended wording changes to the existing PBS listing for using risperidone to treat behavioural disturbances in dementia that had been proposed by the Department and recommended a new listing for risperidone for continuing treatment beyond 12 weeks in patients where there is a benefit and is clinically appropriate. The PBAC noted that the intent of the restriction changes brought forward by the Department is to reduce inappropriate prescribing in patients beyond 12 weeks. The PBAC considered this change should form part of a broader suite of measures to improve the quality use of medicines in people with dementia. The PBAC recommended the level of authority for risperidone for initial listing be Authority Required (STREAMLINED), and for the new continuing listing for BPSD be Authority Required (Telephone), to further support the intent of the changes in reducing inappropriate prescribing of risperidone in BPSD beyond 12 weeks. The PBAC noted there may be practical considerations relating to increasing the level of authority and requested that the Department investigate whether this change could be feasibly implemented. The PBAC noted that the proposed changes would allow the Department to undertake retrospective utilisation analyses and may be used to inform compliance activities. The PBAC was concerned that this change may result in an increase in off-label and private prescribing of other agents known to be prescribed for BPSD. The PBAC recommended that a review of the utilisation of risperidone and other antipsychotics and benzodiazepines be conducted at no later than 2 years following the restriction changes.

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SOMATROPIN All forms and strengths Various Brands Various Sponsors	Severe growth hormone deficiency	To ratify the amended eligibility criteria for the Section 100 (Growth Hormone) Authority Required listing of adult use somatropin.	In July 2019, the PBAC recommended changes to the PBS eligibility criteria (PBS restrictions) for adult use somatropin to provide that childhood onset growth hormone deficiency (CO-GHD) patients with congenital, genetic or structural causes who have previously received PBS-subsidised therapy as children are no longer required to provide provocation tests to meet the eligibility criteria for adult use somatropin. Following feedback from the Endocrine Society of Australia (ESA) about the changes recommended by the PBAC, the PBAC recommended further amendments to the PBS restrictions for adult-use somatropin for CO-GHD patients with a congenital, genetic or structural cause to ensure PBS-subsidised treatment can continue during the transition between skeletal maturity and the chronological age of 18, allowing treatment to commence from when this cohort reaches skeletal maturity rather than the chronological age of 18 years. The PBAC noted that ESA had also proposed additional changes and advised that should the ESA wish to explore further changes to the eligibility criteria of somatropin for the treatment of severe growth hormone deficiency in adults it would welcome a submission from the ESA.
TENOFOVIR DISOPROXIL Various Brands Various Sponsors	Hepatitis B infection	For the PBAC to give advice on recommending hepatitis B antivirals for pregnant women to prevent mother to child transmission and reactivation of hepatitis B after birth; and for the PBAC to consider proposals for listing hepatitis B antivirals for the prevention of reactivation of hepatitis B infection in patients undergoing cancer therapy.	The PBAC recommended amending the listing of tenofovir disoproxil to permit use in patients in the third trimester of pregnancy and up to 12-weeks post-partum in patients with a viral load of >200,000 IU/mL to prevent mother-to-child transmission (MTCT) of hepatitis B infection and to reduce the risk of viral reactivation following giving birth. The PBAC noted the current standard of care to prevent MTCT of hepatitis B infection does not entirely eliminate the risk of transmission. The PBAC considered that this change will reduce these risks further in pregnant women with a high viral load who are currently ineligible for PBS-subsidised antiviral therapy. The PBAC supported, in principle, making tenofovir disoproxil and entecavir available on the PBS for patients identified as at risk of HBV reactivation during cancer therapy. The PBAC noted that, in order to consider the request further, the TGA indications for tenofovir disoproxil and entecavir would need to include this population. The PBAC asked the Department to perform further work to define the population and estimate the potential financial impact of the requested listing, and to contact the relevant sponsors to gauge their willingness to seek a TGA registration for this indication.