SEPTEMBER 2020 PBAC MEETING – OTHER MATTERS

DRUG, SPONSOR, TYPE OF SUBMISSION	DRUG TYPE OR USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
Review of Pharmaceutical Benefits Scheme (PBS) restrictions: levetiracetam (LEV) and lamotrigine (LTG) in women of childbearing potential (all brands)	Medicines for the treatment of epilepsy	For the PBAC to consider the estimated costs to the PBS of expanding the PBS restrictions for LEV and LTG to allow first-line use in women of childbearing potential. To seek the PBAC's advice on issues raised in the written responses from the Epilepsy Society of Australia (ESA) (and endorsed by the Australian and New Zealand Association of Neurologists (ANZAN)).	The PBAC recalled that in March 2020 it requested that the Department of Health conduct research to consider the cost to the PBS of allowing women of childbearing potential to access the second-line anti-epileptic drugs (AEDs), LEV and LTG, first-line. This request followed the PBAC's consideration of feedback from the ESA that best practice clinical management of epilepsy includes the availability of LEV and LTG as first-line agents for women of childbearing potential. The PBAC noted the current PBS restrictions for LEV and LTG restrict access to those who have failed to have their epilepsy controlled with other AEDs. The current restriction may result in prescribers continuing to use sodium valproate among women of childbearing potential when likely safer options are available. The PBAC acknowledged this was a quality use of medicines issue and accepted advice from the ESA on the need for clinicians to have the choice to prescribe alternative AEDs (i.e. LEV and LTG) in this population. The PBAC recommended amending the current PBS restrictions to allow for the first-line use of LEV and LTG in women of childbearing potential. The PBAC accepted the utilisation data and estimates that suggested prescribing of LEV and LTG is already occurring in approximately 75% of women with epilepsy who are of childbearing potential. The PBAC noted that the financial impact to the PBS of expanding the current restrictions was estimated to be small and less than $10 million per year in Year 6. The PBAC considered the additional cost to the PBS of expanding the LEV and LTG restrictions acceptable. Based on the information and clinical guidelines provided by the ESA, the PBAC requested that the Department provide estimates of the cost to the PBS of allowing first-line use of LEV and LTG in the remaining population with epilepsy (i.e. males and females of all ages) to the Drug Utilisation Sub-Committee (DUSC) of the PBAC. In addition, the PBAC requested that the Department provide utilisation data and any further evidence on the broader use of other second-line AEDs to the DUSC in the same report.
Matters relating to PBS Utilisation Review:	Medicines for the treatment of	To provide the PBAC with draft restrictions for PBS-listed	The PBAC recommended the restrictions as proposed allowing twice-daily dosing of standard and high dose PPI medicines for patients with

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Proton pump inhibitors (PPIs) ESOMEPRAZOLE, LANSOPRAZOLE, OMEPRAZOLE, PANTOPRAZOLE, RABEPRAZOLE (All current and previously listed brands, including generic versions)	gastrointestinal acid related disorders including: gastro-oesophageal reflux disease (GORD), peptic ulcer, hypersecretory conditions including Zollinger-Ellison Syndrome and scleroderma oesophagus.	standard and high dose PPI medicines which include patient populations with complex gastro oesophageal reflux disease (GORD) requiring twice daily dosing, as requested at the March 2020 meeting.	complex GORD, and accepted the financial estimates of additional cost to the PBS associated with these restrictions. The PBAC noted the draft restrictions for PBS-listed standard dose PPI medicines were consistent with its advice provided at the March 2020 meeting, and input from the RACGP and GESA that some patients with complex GORD require more than once-daily standard dose PPI therapy to manage their condition. For standard dose PPIs, initial treatment will require prescribing by, or in consultation with a specialist (gastroenterologist/upper GI surgeon), and continuing treatment may be prescribed by a specialist or general practitioner. The PBAC agreed that the Authority Required (Telephone) restriction level would distinguish this restriction from the existing once-daily Authority (Streamlined) standard dose PPI listings for GORD, and maintain the quality use of medicines (QUM) changes achieved since the 1 May 2019 PBS restriction changes to PPI medicines. The PBAC recommended that esomeprazole 20 mg be included as a standard dose PPI medicine to which this restriction applies. Authorisations for increased quantities/repeats for esomeprazole 20 mg have not previously been permitted due to the availability of the 40 mg (high) dose. With respect to high dose PPI medicines, the PBAC considered that the population of patients not covered by existing indications to be very small. The PBAC also considered that the proposed restrictions for PBS-listed esomeprazole 40 mg addressed GESA's concerns that an additional subset of patients require long-term high-dose twice-daily PPI therapy. The PBAC advised the new listings for esomeprazole 40 mg for complex GORD should be restricted to prescribing by a gastroenterologist or upper GI surgeon. The PBAC noted that specialist review is important in this group of patients and therefore the associated cost to patients and the MBS are likely to be incurred regardless of this criterion. The Department will work with the NPS MedicineWise to develop further prescriber and patient educational material on the recommended changes to the PBS restrictions for PPIs, and the release of this information will be

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			timed to accompany the implementation of the PBS restriction changes.
Matters relating to PBS Utilisation Review: Pulmonary Arterial Hypertension (PAH) Medicines AMBRISENTAN BOSENTAN MACITENTAN EPOPROSTENOL ILOPROST SILDENAFIL (20mg, 90 tablets) TADALAFIL (20mg, 56 tablets) RIOCIGUAT (all brands)	Medicines specifically used to treat PAH	To provide the PBAC with draft dual therapy restrictions for PAH medicines from the prostanoid and phosphodiesterase type 5 inhibitor (PDE-5i) classes. For the PBAC to consider the estimated cost to the PBS of extending PBS subsidy to dual therapy with prostanoids and PDE-5i medicines.	The PBAC considered the proposed Pharmaceutical Benefits Scheme (PBS) restrictions for dual therapy with prostanoids (inhaled and intravenous) and phosphodiesterase-5 inhibitor (PDE-5i) medicines as second line treatment for patients with World Health Organisation (WHO) Functional Class (FC) III symptoms and first line treatment for patients with WHO FC IV symptoms. The PBAC also considered the estimated cost to the PBS of extending subsidy to this dual therapy and a Sponsor's pre-PBAC response. The PBAC recalled the clinical evidence presented in the PMR Report supported dual therapy when a PDE-5i medicine is added to a prostanoid (epoprostenol or iloprost) compared with prostanoid monotherapy. Evidence was more limited on use of a prostanoid in addition to an endothelin receptor antagonist (ERA), relative to ERA monotherapy. The PBAC noted patient registry data indicated twice as many PAH patients used prostanoid-ERA combination compared with the prostanoid-PDE-5i combination. Accordingly, the PBAC requested that the Department present PBS restrictions and the estimated cost to the PBS for dual therapy with a prostanoid (iloprost and epoprostenol) and ERA second line for patients with WHO FC III symptoms and first line for patients with WHO FC IV symptoms for future consideration. The PBAC accepted the estimated incremental cost to the PBS of extending subsidy to dual therapy with PAH medicines from the prostanoid (iloprost and epoprostenol) and PDE-5i (sildenafil and tadalafil) classes for patients with WHO FC III and WHO FC IV symptoms. The PBAC considered the financial estimates likely conservative, though overall of low budgetary impact. The PBAC accepted the proposed PBS restrictions in principle, noting that the restrictions will be finalised out of session.
Disease-modifying anti-rheumatic drug (DMARD) treatments required prior to	Rheumatoid Arthritis (RA)	To consider removing the requirement to trial	The PBAC recommended removing the requirement to trial one or more of azathioprine, cyclosporin or sodium aurothiomalate if three or more of

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intial bDMARD authority application for rheumatoid arthritis		azathioprine, cyclosporin or sodium aurothiomalate	methotrexate, hydroxychloroquine, leflunomide and sulfasalazine are contraindicated, from the current restriction for biological medicines for the treatment of rheumatoid arthritis (RA). The PBAC noted that this restriction change would align with current therapeutic guidelines where use of azathioprine, cyclosporin or sodium aurothiomalate is no longer referenced. The PBAC considered that that financial impact of this change will be minimal.
Update to the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM) PrEP guidelines	Human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP)	To request that the prescribing criteria for HIV Pre-Exposure Prophylaxis (PrEP) medications be updated to align with current Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM) PrEP guidelines (released September 2019)	The PBAC recommended amending the listing of tenofovir disoproxil with emtricitabine (TD/FTC) for pre-exposure prophylaxis (PrEP) against HIV infection to allow use in a broader population of at-risk individuals, following the 2019 update to the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM) Guidelines. The PBAC also recommended that the restriction type could be changed from Streamlined Authority to Restricted Benefit. In recommending this change, the PBAC noted the price of TD/FTC has decreased by approximately 50% since the PrEP indication was listed in April 2018 and the use of PrEP has not been greater than expected. Given the current annual per-patient cost of daily PrEP (based on 1 August 2020 prices), the PBAC considered that use in a broader population of individuals who are at risk of acquiring HIV would be acceptably cost effective. Accordingly, the PBAC considered to removal of prescriptive restriction text based on the level of risk of HIV infection would provide flexibility for clinical judgement and case-by-case decision-making.
Review of Palliative Care Schedule and stakeholder consultation	Palliative Care	To consider the Palliative Care Schedule Review and input from stakeholders in relation to the Palliative Care Schedule (PCS).	The PBAC considered the proposals from the review of the Palliative Care Schedule (PCS), including input from the Royal Australian College of General Practitioners and Palliative Care Australia in relation to the retention, deletion and amendment of items on the PCS. The PBAC considered there was an ongoing need for a PCS in addition to the General Schedule in order to provide palliative care patients with flexible access to medicines. The PBAC considered that aligning PCS opioid listings with the recent changes to the General Schedule would support the appropriate

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			prescribing and use of opioids. The PBAC maintained its intent to support quality use of opioids while not impacting appropriate supply of opioids to palliative patients. The PBAC recommended PCS listings for a number of opioids for both short-term use (hydromorphone tablets, injections, oral liquid; morphine injections and oral liquid) and long term-use (morphine modified release tablets, capsules and granules; oxycodone modified release tablets, oxycodone with naloxone modified release tablets, fentanyl transdermal patches, hydromorphone modified release tablets, methadone tablets and injection). For opioids for long-term use, the PBAC recommended Authority Required (telephone) listings which provide a maximum quantity for 4 weeks treatment, consistent with the current listings. For opioids for short-term use the PBAC recommended listings with a maximum quantity or 2 with 1 repeat noting that dosing would vary considerable between patients. The PBAC considered that some of the restrictions applicable to authority requests for increased maximum quantities or repeats in the General Schedule opioid listings could be eased for the corresponding PCS listings. The PBAC recommended removing the PCS listings for bisacodyl, diclofenac 100 mg suppository and indometacin as there are corresponding General Schedule listings for these medicines with similar maximum quantities and repeats. The PBAC noted that clonazepam tablets and oral liquid have Authority Required (telephone) listings for myoclonus under the PCS. The PBAC acknowledged that in palliative care, clonazepam may have a broader use and considered it would be appropriate for the indication to read “For use in patients receiving palliative care.” The PBAC also recommended an Authority Required (STREAMLINED) PCS listing for clonazepam 1 mg injection with one additional repeat compared to the current listing. The PBAC recommended a PCS listing for metoclopramide 10 mg tablets with a maximum quantity of 100 units and 5 repeats noting that the current Unrestricted Benefit listing provides only a maximum quantity of 25 units with no repeats. The PBAC also recommended amending the existing PCS listing of metoclopramide 10 mg injection to include two repeats.

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			The PBAC considered that the PCS should be reviewed in the future to ensure its listings remain appropriate in the palliative care setting.
Authority level for bDMARD continuing treatment	Various	To consider the request from the Australian Rheumatology Association that the authority level for all bDMARDs be amended to streamlined for continuing treatment.	The PBAC did not recommend changing the restriction for the "continuing" treatment phase of innovator biological medicines, without a biosimilar, from Authority Required (written) to Authority Required (STREAMLINED). In making its recommendation, the PBAC noted that the effects that biosimilar drivers for etanercept, rituximab and infliximab were having on prescriber behaviour were consistent with the intent of the biosimilar strategy, and that no new evidence of patient safety, efficacy and outcomes were presented. The PBAC recognised that current restrictions have a modest impact on patients. The PBAC endorsed real time assessment and approval of innovator biological medicines via Services Australia PBS Online Authorities System for restrictions in the continuing treatment phase to facilitate access to bDMARDs.
Prescriber Bag listings for oral furosemide and oral antimicrobials	Prescriber Bag	To consider the request from the Royal Australian College of General Practitioners to add oral forms of furosemide and antimicrobials to the Prescriber Bag.	The PBAC recommended the addition of oral furosemide 20 mg to the Prescriber Bag. The PBAC considered that the addition of furosemide was appropriate to facilitate the urgent pre-hospital management of heart failure. The PBAC did not recommend the addition of cephalexin, nitrofurantoin or trimethoprim to the Prescriber Bag. The PBAC considered that adding cephalexin and nitrofurantoin to the Prescriber Bag was not consistent with antimicrobial stewardship and the quality use of medicines for antibiotics. The PBAC further considered that in the case of trimethoprim, the policy intent of the Prescriber Bag was to provide true emergency items to reduce preventable hospitalisations, which is unlikely in urinary tract infections.