PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
SEPTEMBER 2025 PBAC MEETING

The PBAC outcomes and recommendations are presented in alphabetical order by drug name.

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME	
DAPAGLIFLOZIN Tablet 10 mg (as propanediol monohydrate) Forxiga ASTRAZENECA PTY LTD Category 3 (Change to existing listing)	Chronic kidney disease (CKD)	To consider amending the General Schedule Authority Required (STREAMLINED) listing for the treatment of CKD to align with the broader population recommended in May 2025 for empagliflozin.	Recommended	The PBAC recommended expanding the eligible population for the PBS listing for dapagliflozin for the treatment of adult patients with CKD to include a larger population that is in line with its May 2025 recommendation for empagliflozin. The additional population for the expanded listing includes 4 distinct subgroups of patients with: • estimated Glomerular Filtration Rate (eGFR) 20 to <25 mL/min/1.73 m^2 regardless of urinary albumin to creatinine ratio (UACR) • eGFR 25 to <45 mL/min/1.73 m^2 with UACR <200 mg/g • eGFR 25 to 75 mL/min/1.73 m^2 with UACR >5,000 mg/g • eGFR >75 to 90 mL/min/1.73 m^2 with UACR ≥200 mg/g The PBAC noted and welcomed consumer inputs from health care professionals and organisations received after the publication of the empagliflozin outcome from the May 2025 meeting. The PBAC acknowledged that the benefits of sodium-glucose cotransporter 2 (SGLT2) inhibitors such as dapagliflozin and empagliflozin extend to a broader CKD population and the support for the alignment of the dapagliflozin with empagliflozin restrictions was based on evidence from clinical trials, real-world data and international clinical practice guidelines. Additionally, the PBAC agreed with the consumer inputs' arguments that aligning dapagliflozin with empagliflozin restrictions would improve quality use of medicines and provide equitable access for patients and clinical clarity for prescribers for this class of medicine. The PBAC considered that the submission provided adequate evidence to align the dapagliflozin restrictions with empagliflozin. This included the update to the current Therapeutic Goods Administration approved indication for dapagliflozin, current clinical guidelines for CKD treatment with SGLT2 inhibitors, and real-world evidence that in the requested additional population, dapagliflozin had a similar benefit to empagliflozin. The PBAC recommended listing dapagliflozin on a cost-minimisation basis to empagliflozin (Jardiance®). The PBAC advised the equi-effective doses to be empagliflozin 10 mg once per day and dapagliflozin 10 mg once per day.

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MOGAMULIZUMAB Solution concentrate for I.V. infusion 20 mg in 5 mL Poteligeo Kyowa Kirin Australia Pty Ltd Matters arising from the minutes (New PBS listing)	Cutaneous T-cell lymphoma (CTCL)	To consider the sponsor's proposal for listing mogamulizumab for the treatment of CTCL. This matter was considered at the March 2025 PBAC Meeting.	Advice Provided	The PBAC provided additional advice in relation to its March 2025 recommendation for listing mogamulizumab on the PBS for the treatment of patients with cutaneous T-cell lymphoma that has reappeared after, or not responded to, initial treatment (relapsed or refractory CTCL). The PBAC recalled its previous advice that there was a high clinical need for alternative therapies to treat this rare disease, and its advice that mogamulizumab has a unique mechanism of action which would be particularly useful in patients with blood compartment involvement. The PBAC considered that a small premium over the previously recommended cost-minimisation approach was appropriate to reflect the additional benefits that these patients would receive with mogamulizumab treatment.

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NIVOLUMAB + IPILIMUMAB NIVOLUMAB Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL Opdivo® IPILIMUMAB Injection concentrate for I.V. infusion 50 mg in 10 mL Injection concentrate for I.V. infusion 200 mg in 40 mL Yervoy® BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD Matters outstanding (Change to existing listing)	Unresectable advanced and metastatic cancer	To consider a proposal for an expanded listing to facilitate broad access for the treatment of unresectable advanced and metastatic cancer. This matter was deferred at the July 2025 PBAC Meeting.	Recommended	The PBAC recommended a multi-indication (broad) listing for nivolumab and ipilimumab in advanced or metastatic cancers. The PBAC considered the revised proposal put forward by the sponsor addressed its concerns, particularly in ensuring the financial risk was acceptably contained within the proposed risk sharing arrangement. The PBAC noted the recommended wording for the listing would allow clinicians to apply clinical judgment and discretion in using the medicines according to the best available evidence at the time, including for retreatment, extended time on treatment and rare cancers for which regulatory submissions are unlikely. The listing would also remove the once in a lifetime limitation for these medicines when used for advanced or metastatic cancers. The PBAC acknowledged the significant amount of work that had gone into developing this proposal from the sponsor and the Department, as well as the support from a range of consumer and clinical representative bodies. The PBAC was pleased to have found an agreeable way forward for this novel approach to medicines funding under the PBS and hoped this may serve as a framework for future proposals of this kind. The PBAC noted that successful implementation and appropriate use of this listing would be crucial to support considerations of both this and any similar future broad listing proposals. The PBAC reiterated the importance of engagement from the sponsor, patient groups, clinical peak bodies and healthcare practitioners in supporting the ongoing viability of the listing. The PBAC requested the Department review how the listing was being used after three years to ensure the use remained consistent with its intention.

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OSIMERTINIB Tablet 40 mg Tablet 80 mg Tagrisso® ASTRAZENECA PTY LTD Early re-entry (Change to existing listing)	Non-small cell lung cancer (NSCLC)	To request a General Schedule Authority Required (Telephone/Online) listing for the first line treatment of Stage IIIB (locally advanced) or Stage IV (metastatic) epidermal growth factor receptor mutation-positive (EGFRm) NSCLC in combination with pemetrexed and platinum-based chemotherapy.	Recommended	The PBAC recommended the listing of osimertinib, in combination with chemotherapy, for the first-line treatment of patients with locally advanced or metastatic NSCLC with evidence of an activating epidermal growth factor receptor mutation (EGFRm) in tumour material. The PBAC considered the early re-entry resubmission had addressed the outstanding issues from its May 2025 consideration (see the public summary document for more detail). The PBAC considered a single osimertinib restriction covering all patient populations with EGFRm NSCLC was appropriate and the methodology proposed in the pre-PBAC response for calculating a price for this listing was appropriate.
VANZACAFTOR WITH TEZACAFTOR AND WITH DEUTIVACAFTOR Pack containing 84 tablets vanzacaftor 4 mg with tezacaftor 20 mg and with deutivacaftor 50 mg Pack containing 56 tablet vanzacaftor 10 mg with tezacaftor 50 mg and with deutivacaftor 125 mg Alyftrek® VERTEX PHARMACEUTICALS PTY LTD Matters outstanding (New PBS listing)	Cystic fibrosis	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of cystic fibrosis in patients who are aged 6 years and older and who have at least one F508del mutation or another responsive mutation in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene. This matter was deferred at the July 2025 PBAC Meeting.	Recommended	The PBAC recommended the Section 100 (Highly Specialised Drugs Program) listing of vanzacaftor with tezacaftor and with deutivacaftor (VNZ/TEZ/D-IVA) for the treatment of cystic fibrosis in patients aged 6 years and older who have at least one mutation in the *CFTR* gene that is responsive to VNZ/TEZ/D-IVA potentiation based on clinical and/or in vitro assay data. The PBAC welcomed input from clinicians and consumers for the July 2025 meeting. The PBAC acknowledged there was strong support for the listing of this medicine. The PBAC noted consumer inputs that VNZ/TEZ/D-IVA would provide a once daily treatment option for patients with responsive mutations. Additionally, the PBAC noted VNZ/TEZ/D-IVA would provide access to a CFTR modulator for a small number of patients (<500) who have mutations that do not respond to elexacaftor, tezacaftor and ivacaftor (ELX/TEZ/IVA, Trikafta®). The PBAC considered VNZ/TEZ/D-IVA was as effective and safe as ELX/TEZ/IVA, and noted the submission requested listing at a similar cost as ELX/TEZ/IVA. The PBAC considered that VNZ/TEZ/D-IVA could be included in the risk sharing arrangement currently in place for CFTR modulators with no increase in expenditure caps. The PBAC noted flow-on changes to the CFTR modulator PBS listings for cystic fibrosis were required to include reference to VNZ/TEZ/D-IVA.

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ZOLBETUXIMAB Powder for I.V. infusion 100 mg (20 mg per mL) Vyloy® ASTELLAS PHARMA AUSTRALIA PTY LTD Matters outstanding (New PBS listing)	Gastric or gastroesophageal junction (G/GOJ) cancer	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the first-line treatment of locally advanced unresectable or metastatic epidermal growth factor receptor 2-negative G/GOJ adenocarcinoma whose tumours are CLDN18.2- positive. This matter was deferred at the March 2025 PBAC Meeting.	Recommended	The PBAC recommended the PBS listing of zolbetuximab in combination with chemotherapy for the treatment of patients with G/GOJ cancer that: cannot be removed by surgery or has metastasised to other parts of the body; is HER2-negative (a common cancer marker); and has a specific protein called Claudin 18.2 on the surface of the cancer cells, which enables zolbetuximab to target cancer cells in those patients. The Medical Services Advisory Committee has now recommended Medicare Benefits Schedule listing of pathology testing to detect Claudin 18.2 on the patient's cancer cells. The PBAC noted that at its March 2025 meeting it considered that there is a clinical need for new treatments for G/GOJ cancer as there are few effective treatment options, and prognosis with current treatments remains poor. The PBAC considered that zolbetuximab was as effective as nivolumab at slowing cancer progression and improving survival. The PBAC noted that compared to nivolumab, use of zolbetuximab in combination with chemotherapy caused higher rates of severe nausea, vomiting and appetite loss. The PBAC therefore considered that the price for zolbetuximab should reflect the potential for these side effects to impact patients' quality of life.

Version 2

Amendment:

1. VANZACAFTOR WITH TEZACAFTOR AND WITH DEUTIVACAFTOR – Replaced PBAC outcome wording 'and noted the submission requested the same price' with 'and noted the submission requested listing at a similar cost'

Other items considered where the PBAC provided advice

AGENDA ITEM, FORM(S), STRENGTH(S), SPONSOR, TYPE OF AGENDA ITEM	DRUG TYPE AND USE	PURPOSE OF AGENDA ITEM	PBAC OUTCOME
Post Market Review (PMR) work plan Various drugs, strengths, brands and	Various indications	To provide the PBAC with an update on the status of current post-market review	The PBAC provided advice on the updated Post-market Review workplan, which includes the status of current and recently completed projects, as well as new projects recently requested by the PBAC relating to Pulmonary Arterial Hypertension and lamotrigine for the treatment of bipolar disorder. The PBAC noted that there are currently no

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sponsors Post-market review (PBS review)		research projects for noting and request PBAC advice on the Attention Deficit Hyperactivity Disorder (ADHD) medicine review.	formal Post-market Reviews are underway and did not recommend any new Post-market Review topics. The PBAC agreed for the Department to undertake a research project to review the PBS listings for the treatment of ADHD. This research project will explore topics recommended for review by the Senate Community Affairs References Committee in its inquiry into the assessment and support services for people with ADHD, which was supported in-principle by Government in December 2024 subject to agreement by the PBAC to undertake a review. The PBAC advised that this work should be done as a research project, rather than necessitating a formal Post-market Review.
Prescriber Bag Review Various drugs, strengths, brands and sponsors Post-market review (Change to existing listing)	Multiple-emergency drug supplies	To review the items currently listed in the PBS Prescriber Bag so emergency patient care is supported through the inclusion of pharmaceutical benefits that reflect contemporary best emergency practice and are efficacious and safe. To consider stakeholder requests for potential inclusion of additional items in the Prescriber Bag. To consider the Prescriber Bag utilisation analysis. To make recommendations for items that should be added to or removed from the Prescriber Bag.	The PBAC provided advice on findings from the first tranche of a Review of PBS Prescriber Bag medicines. The PBAC considered consolidated stakeholder input received from a targeted consultation process and considered requests for the removal of items, addition of new strengths of existing items, new items to replace current items, and increased maximum quantities. The PBAC considered the stakeholder requests by applying an algorithm developed by the Department intended to support the PBAC's consideration of the suitability of a medicine to be listed or retained as a Prescriber Bag benefit. The PBAC also considered advice from the Drug Utilisation Sub-Committee (DUSC) on the utilisation of existing PBS Prescriber Bag items. The PBAC recommended that all currently listed Prescriber Bag benefits remain suitable, except molnupiravir 200 mg tablet and nirmatrelvir 150 mg tablet & ritonavir 100 mg tablet, (COVID-19 antiviral medicines) and furosemide tablets. The PBAC recommended that COVID-19 anti-viral medicines be removed, acknowledging that stakeholders may hold disparate views but that the clinical landscape had evolved from the time of Prescriber Bag listing. The PBAC considered the potential for wastage of furosemide tablets due to the pack size (50) but noted support from stakeholders to retain this item in the PBS Prescriber Bag. The PBAC deferred making its recommendation on furosemide and requested the Department investigate with sponsors the availability of a smaller pack size which may decrease wastage. The PBAC recommended the addition of ceftriaxone 2 g injection on the Prescriber Bag, noting support from multiple stakeholders for the emergency treatment of sepsis. The PBAC did not recommend the remaining stakeholder requests for additional strengths of existing items and new items to replace current items, noting that these items did not meet the algorithm criteria of Therapeutic Goods Administration registration for the requested indication and/or PBS listing, and that this was a significant barrier to inclusion. In considering a request from the Australian College of Midwives (ACM), the PBAC recommended that the PBS listings of benzathine benzylpenicillin (Prescriber Bag and the General Schedule) and adrenaline injections (Prescriber Bag) be amended to allow prescribing by endorsed midwives. The PBAC considered that extending prescribing of benzathine benzylpenicillin to endorsed midwives would harmonise best practice standards, facilitate earlier intervention, improve maternal and neonatal outcomes by reducing congenital syphilis cases, and support the National syphilis response. The PBAC considered that extending prescribing of adrenaline to midwives would support their practice as immunisation providers and as first responders in emergency care.

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Submission category types

Category 1	A request for PBS or NIP listing of one or more of the following: • A first in class medicine or vaccine, and/or a medicine or vaccine for a new population. OR • A drug with a codependent technology that requires an integrated codependent submission to the PBAC and MSAC. OR • A drug or designated vaccine with a TGA Provisional determination related to the proposed population.
Category 2	A request for PBS or NIP listing of a new medicine or new vaccine, a new indication of a currently listed medicine or vaccine, or to make material changes to a currently listed indication and do not meet the criteria for a Category 1 submission.
Category 3	Requests to change existing listings that do not change the population or cost effectiveness of the medicine or vaccine that do not meet the criteria for a Category 4 submission.
Category 4	A request for one or more of the following: • Listing of a new pharmaceutical item of a listed medicine. • Consideration as an exempt item (Exempt item as per subsection 84AH of the *National Health Act 1953*). • Including a listed medicine on the prescriber bag or varying an existing prescriber bag listing. • A change/new manner of administration of a listed medicine. • A change to the maximum quantity and/or number of repeats of a listed medicine. • A change or addition to the prescriber type(s) of a listed medicine.
Committee Secretariat	Application is not in Categories 1, 2, 3 or 4 and requests for one or more of the following: • New or varied listed drugs, medicinal preparations and designated vaccines that pose no greater risk. • Pharmaceutical benefits that can no longer be supplied early. • New brand of glucose indicator pharmaceutical item.

Resubmission pathways

There are four different resubmission pathways available to applicants following a 'not recommended' PBAC outcome. Resubmission pathways are not available for submissions that receive a positive recommendation from the PBAC. The resubmission pathways are classified into the following categories:	
Standard re-entry	The Standard Re-entry Pathway is the default pathway for resubmissions and also applies where: • an applicant chooses not to accept the PBAC nominated resubmission pathway; or • an Early Re-entry or Early Resolution Pathway has been nominated by the PBAC and an applicant decides to address issues other than those identified by the PBAC (including a subset of issues); or • an applicant decides to lodge later than the allowable timelines for the other pathways.
Early re-entry pathway	An Early Re-entry Pathway may be nominated by the PBAC where the PBAC considers that the remaining issues could be easily resolved and the medicine or vaccine does not represent High Added Therapeutic Value (HATV) for the proposed population. Applicants who accept this pathway are eligible for PBAC consideration at the immediate next meeting.
Early resolution pathway	For medicines or vaccines deemed by the PBAC to represent HATV AND where the PBAC considers that the remaining issues could be easily resolved, including when: • new clinical study data requiring evaluation is not considered necessary by the PBAC to support new clinical claims to be made in the resubmission; and • a revised model structure or input variable changes (beyond those specified by the PBAC) are not necessary to support any new economic claims, or to estimate the utilisation and financial impacts to be made in the resubmission. Applicants who accept this pathway are eligible for PBAC consideration out-of-session (before the main meeting), unless the department, in consultation with the PBAC Chair, identifies an unexpected issue such that the resubmission needs consideration at the next main PBAC meeting.
Facilitated resolution pathway	A Facilitated Resolution Pathway may be nominated by the PBAC where the PBAC considers the issues for resolution could be explored through a workshop AND where the medicine or vaccine meets the HATV criteria. Applicants who accept this pathway are eligible for a solution-focussed workshop with one or more members of the PBAC. The workshop agenda will be based on the issues for resolution outlined in the PBAC Minutes. This can be further clarified during the post-PBAC meeting with the Chair.