PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
May 2026 PBAC MEETING

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

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, CATEGORY/TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME	OUTCOME DETAILS
ADALIMUMAB and INFLIXIMAB ADALIMUMAB: Injection 20 mg in 0.2 mL pre-filled syringe Injection 20 mg in 0.4 mL pre-filled syringe Injection 40 mg in 0.4 mL pre-filled syringe Injection 40 mg in 0.4 mL pre-filled pen Injection 40 mg in 0.8 mL pre-filled syringe Injection 40 mg in 0.8 mL pre-filled pen Injection 80 mg in 0.8 mL pre-filled syringe Injection 80 mg in 0.8 mL pre-filled pen INFLIXIMAB: Powder for I.V. infusion 100 mg Various brands and sponsors Internal submission (Change to existing listing)	Crohn disease (CD)	To consider amendments to the adalimumab and infliximab listings that permit dosing flexibility for the paediatric treatment of moderate to severe CD.	Recommended	The PBAC recommended that the PBS listings for infliximab intravenous infusion for paediatric patients with moderate to severe ulcerative colitis (UC), acute severe UC and moderate to severe CD be amended to allow dose escalation and more flexible dosing. This includes enabling doctors to increase the dose and adjust how often the medicine is given when clinically needed. The PBAC noted and welcomed the input from the Gastroenterological Society of Australia on this matter. The PBAC recognised need for effective treatment options in children, who have fewer PBS listed advanced therapies for inflammatory bowel (IBD) disease than adults and may experience serious consequences from disease, such as impaired growth and development. The PBAC also noted evidence suggesting that, when doses are calculated on a weight basis, children may require relatively higher doses than adults to achieve the same treatment effect. The PBAC advised that it was satisfied that there was sufficient evidence (including international guidelines) to support that flexible dosing of infliximab, guided by appropriate therapeutic drug monitoring, improves outcomes for children with IBD over standard dosing, particularly those who are younger, have more severe disease, or have certain clinical factors such as low albumin levels. The PBAC also considered that escalated dosing of infliximab, where clinically appropriate, is already widely used in Australian clinical practice. The PBAC advised that the increased utilisation of infliximab resulting from escalated dosing was likely to be cost-effective at the current price. The PBAC acknowledge that these changes were limited to the paediatric population and that this may create challenges, particularly during the transition to adulthood. However, the PBAC considered that applying the changes to the paediatric population only was acceptable at this time considering additional disease associated risks and that there are fewer available treatment options compared to adults. The PBAC advised that further work is needed to consider similar dosing flexibility of infliximab for adult patients and for children transitioning into adulthood, and that future submissions from sponsors should address these issues.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
May 2026 PBAC MEETING

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FEDRATINIB Capsule 100 mg Inrebic® BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD Matters arising from the minutes (Change to existing listing)	Myelofibrosis (MF)	To consider a request to update the PBS restrictions for ruxolitinib and momelotinib so they align with the PBS-listed restrictions for fedratinib, as recommended at the November 2025 meeting.	Recommended	The PBAC recommended that the number of repeats of the fedratinib restrictions for the initial treatment of MF be flowed on to the listings of momelotinib and ruxolitinib (from 0 repeats to 5 repeats) for the same indication. The PBAC considered that consistency in the number of repeats across all Janus Kinase (JAK) inhibitors for the treatment of MF was appropriate because it considered that momelotinib, ruxolitinib and fedratinib were all comparable treatment options for this condition.
MIGALISTAT Capsule containing migalastat hydrochloride 150 mg Galafold® AMICUS THERAPEUTICS PTY LTD Matter arising from the minutes (Pricing matter)	Fabry Disease	To confirm the approach for adjusting the risk-sharing arrangement caps recommended at its March 2026.	Advice provided	The PBAC advised that an adjustment to the current expenditure caps for migalastat for Fabry disease is reasonable to reflect utilisation analyses provided by DUSC in March 2026. The PBAC noted the migalastat utilisation following its transition from the LSDP to the PBS, particularly around the differences from the original estimates and the impact of the amendment to the cardiac criterion within the migalastat restriction.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
May 2026 PBAC MEETING

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, CATEGORY/TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME	OUTCOME DETAILS
RANIBIZUMAB Solution for ocular implant 39.5 mg in 0.395 mL Susvimo® Roche Products Pty Ltd Matters outstanding (Change to existing listing)	Neovascular (wet) age-related macular degeneration	To reconsider ranibizumab delivered via a port delivery system followed a deferred outcome at the March 2022 PBAC meeting.	Not Recommended	The PBAC did not recommend the listing of ranibizumab delivered through a port delivery system (PDS) (a surgically inserted eye implant), for the treatment of neovascular age-related macular degeneration (nAMD) in patients who have previously responded to intravitreal anti-vascular endothelial growth factor (anti-VEGF) treatment. At its March 2022 meeting, the PBAC deferred making a recommendation for listing ranibizumab PDS to await further information from the Therapeutic Goods Administration (Australia's regulator of medicines and other therapeutic goods) that it would approve the medicine, and for the Medical Services Advisory Committee to consider the procedure used to implant the PDS. In late 2022, the sponsor paused regulatory activities in Australia due to concerns regarding the performance of the PDS. The Sponsor is currently seeking TGA approval for an updated version of the PDS. Noting the previous decision was made over 4 years ago and the pending TGA decision for the updated PDS, the PBAC considered that a resubmission would be an appropriate next step to progress ranibizumab PDS towards PBS listing. **Sponsor Comment:** Roche is currently pursuing TGA registration and will provide a PBAC re-submission in due course.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
May 2026 PBAC MEETING

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, CATEGORY/TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME	OUTCOME DETAILS
RAXTOZINAMERAN (BNT162b2-platform COVID-19 Vaccine) I.M. injection, suspension for injection containing raxtozinameran 30 micrograms Comirnaty® Omicron XBB.1.5 PFIZER AUSTRALIA PTY LTD Matter arising from the minutes (Pricing matter)	Prevention of coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2	To consider a revised pricing offer for National Immunisation Program listing of BNT162b2-platform COVID-19 vaccine.	Recommended	The PBAC reaffirmed its December 2025 recommendation for National Immunisation Program (NIP) listing of the BNT162b2 platform (Comirnaty) vaccines, for prevention of coronavirus disease 2019 (COVID-19) caused by SARS CoV-2 virus in four populations of adults as requested by the sponsor. The four populations include: 1) Adults aged 75 years or more (2 doses per year); 2) Adults aged 65-74 years (1 dose per year); 3) Adults aged 18-64 years with severe immunocompromise (1 dose per year); and 4) Aboriginal and Torres Strait Islander adults aged 50 to 74 years (1 dose per year). This is a smaller group than the group eligible under current arrangements for the National COVID-19 Vaccination Program (NCVP). The PBAC considered Comirnaty again at its May 2026 meeting for the purpose of reviewing a new price put forward by the sponsor, Pfizer. Since the PBAC did not consider any new clinical data, its conclusions about the clinical evidence were unchanged from its advice in December 2025. Consistent with its advice in December 2025, the PBAC supported a platform approach to the PBAC consideration, meaning that the PBAC recommendation will apply to future adaptations of the BNT162b2 vaccines, manufactured using the same technology as used for Pfizer's earlier Comirnaty vaccines. This will support the introduction of future Comirnaty vaccines to ensure the community has access to the latest vaccine through the NIP following approval by the Therapeutic Goods Administration, Australia's regulator of medicines and other therapeutic goods. The PBAC considered that the vaccine would be cost-effective at the new price proposed. However, the PBAC considered that there was still some uncertainty about how cost-effective future versions of the vaccine would be. To address this, the PBAC advised that the cost-effectiveness and the extent of use of Comirnaty should be reviewed within 3 years of listing on the NIP. The PBAC considered that Pfizer should be required to lodge a PBAC submission with this information so that it could be reviewed by the PBAC. The PBAC noted the high financial impact associated with the listing Comirnaty on the NIP, and the new and unique situation of moving from the NCVP to the NIP.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
May 2026 PBAC MEETING

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, CATEGORY/TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME	OUTCOME DETAILS
RESPIRATORY SYNCYTIAL VIRUS VACCINE* Solution for injection 50 µg in 0.5 mL pre-filled syringe mResvia® MODERNA AUSTRALIA PTY LTD Matter outstanding (New NIP listing)	Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)	To request a National Immunisation Program listing for the prevention of lower respiratory tract disease caused by RSV in individuals aged over 75 years and Aboriginal and Torres Strait Islander people aged over 60 years based on the supply of the additional information from the Department.	Not Applicable	To be considered at a future PBAC meeting.
TARLATAMAB Powder for injection 1 mg Powder for injection 10 mg Imdelltra® AMGEN AUSTRALIA PTY LIMITED Matter arising from the minutes (Other matters)	Extensive-stage small cell lung cancer (ES-SCLC)	To consider amendments to the tarlatamab minutes of the March 2026 PBAC meeting.	Advice provided	The PBAC provided additional advice for tarlatamab, for the treatment of ES-SCLC with disease progression on or after first line treatment of platinum-based chemotherapy, previously considered at the March 2026 PBAC Meeting. The PBAC considered that for this patient population, tarlatamab met the 'high added therapeutic value' (HATV) criteria as it addressed a high and urgent unmet clinical need and provided a substantial and clinically relevant improvement in efficacy compared to standard of care (SOC) chemotherapies.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
May 2026 PBAC MEETING

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, CATEGORY/TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME	OUTCOME DETAILS
TUCATINIB Tablet 50 mg; Tablet 150 mg TUKYSA® Pfizer Australia Pty Ltd Matter arising from the minutes (Pricing matter)	Breast cancer	To reconsider the November 2025 recommended pricing following a revised proposal from the sponsor.	Advice provided	The PBAC provided advice in relation to a pricing proposal received for tucatinib for use in combination with trastuzumab plus capecitabine for the treatment of metastatic (Stage IV) human epidermal growth factor receptor 2 positive (HER2+) breast cancer in patients who have received two prior lines of HER2-directed therapy or who have progressed on trastuzumab deruxtecan. Tucatinib was recommended for listing on the PBS for this population at the November 2025 PBAC meeting. The sponsor's proposal requested a substantially higher price than requested in its November 2025 submission, but no additional evidence was provided to support this request. The PBAC's view regarding the effectiveness, cost-effectiveness and estimated usage of tucatinib remained unchanged from the November 2025 meeting. The PBAC's advice about tucatinib from its November 2025 meeting included that a reduction in the drug cost would be required for tucatinib to be considered cost-effective versus trastuzumab and capecitabine alone. The PBAC did not accept that tucatinib would replace trastuzumab emtansine (T-DM1) and therefore this comparison was not considered relevant. The PBAC again acknowledged the significant challenges faced by people (on their third or later line of treatment) living with metastatic HER2-positive breast cancer and the substantial impact of this condition on quality of life. The PBAC recognised that, while several treatments are available on the PBS, there is a need for more effective options for people whose cancer has progressed after multiple lines of therapy, especially for those with brain metastases. Further, the PBAC considered that tucatinib may provide a greater benefit and meet a higher clinical need in the group of patients with brain metastases (compared with the broader group proposed for PBS listing) but noted that the sponsor did not want to limit use to this patient group.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
May 2026 PBAC MEETING

Other agenda items

AGENDA ITEM, FORM(S), STRENGTH(S), SPONSOR	DRUG TYPE AND USE	PURPOSE OF AGENDA ITEM	PBAC OUTCOME
Designated Registered Nurse Prescribing	Not applicable	To consider the Tranche 1 and Tranche 2 lists of medicines for designated RN prescribing suitability.	The PBAC recommended that PBS listings for the majority of alimentary tract, cardiovascular system, genitourinary system and antiparasitic medicines (Tranche 1) be amended to add designated registered nurse prescribers as authorised prescribers. The PBAC noted that prescribing will require a prescribing agreement between an individual designated registered nurse prescriber with an authorised health practitioner. The PBAC did not recommend declaring designated registered nurse prescribers as authorised prescribers for a small number of medicines in Tranche 1 for reasons arising from the complexity of the medical condition or where the PBAC considered there to be a significant risk of prescribing outside of the PBS restrictions.
PD-(L)1 inhibitors - Sponsor guidance to seek broad (multi-cancer) listing of PD-(L)1 inhibitors	Not applicable	To consider and advise on drafted departmental guidance for sponsors seeking a broad listing of PD-(L)1 inhibitors	The PBAC endorsed the principles of the drafted departmental guidance for sponsors seeking broad listings for PD-(L)1 inhibitors. The PBAC provided advice and clarifications to be incorporated into the guidance.
Post Market Review (PMR) Workplan	Not applicable	To provide the PBAC with an update on the status of current post-market review research projects and the implementation of recently completed work.	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. This includes new research projects on medicines used off-label or outside PBS arrangements by Aboriginal Community Controlled Health Organisations; potential barriers to access for adrenaline; and a review of PBS-listed medicines for relapsed or refractory multiple myeloma. The PBAC considered representations from the National Aboriginal Community Controlled Health Organisation (NACCHO) and Northern Territory (NT) Health to consider expanding the PBS subsidy arrangements of azithromycin in response to the diphtheria outbreak. The PBAC considered that decisions on PBS subsidy must consider implications for the Commonwealth beyond the immediate emergency response to the diphtheria outbreak. The PBAC asked the Department to undertake further work on potential changes to the PBS subsidy arrangements for azithromycin. This will be considered at the PBAC's next meeting in July 2026. The PBAC noted that there are currently no formal Post-market Reviews underway and did not recommend any new Post-market Review topics.
Review of Pulmonary Arterial Hypertension (PAH) Listings Various drugs, strengths, brands, and sponsors Post-market review (PBS review)	Pulmonary arterial hypertension	To consider restriction amendments for PAH medicines to allow clinicians the option of initiating/escalating treatment based on mortality risk, rather than only based on World Health Organisation (WHO) functional class.	The PBAC recommended the incorporation of risk assessment (risk of mortality within 1 year using a validated risk assessment calculator) as an additional option to assessment of WHO functional class status to guide treatment eligibility for PBS-listed PAH medicines. The PBAC accepted that the investigations and clinical observations included in the various validated risk assessment calculators already occur in practice and that the incorporation of risk assessment into the PBS restrictions would bring further alignment of PBS restrictions with clinical practice and international treatment guidelines. The PBAC expected minimal financial impact as a result of the change. The PBAC expressed a preference for Option 2 (a simplified approach) over Option 1 (the current restriction format containing numerous treatment phases) pending further consultation with subject matter experts.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
May 2026 PBAC MEETING

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			UPDATE post May 2026: The PBAC noted that feedback received was overall supportive of Option 2 (simplified approach) for the proposed restriction changes and re-affirmed its May 2026 recommendation to incorporate risk assessment (12-month mortality) into the PBS restrictions in the style of Option 2.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
May 2026 PBAC MEETING

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.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
May 2026 PBAC MEETING

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.