

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
MAY 2024 PBAC MEETING**

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

Submission items

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME	
<p align="center">AFLIBERCEPT</p> <p>Solution for intravitreal injection 11.34 mg in 100 microlitres (114.3 mg per mL)</p> <p align="center">Eylea®</p> <p align="center">BAYER AUSTRALIA LTD</p> <p align="center">(New PBS listing)</p>	<p align="center">Diabetic macular oedema (DMO)</p>	<p align="center">To request a General Schedule Authority Required (Written) listing for the treatment of patients with visual impairment due to DMO.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the Authority Required listing of aflibercept 8 mg for the treatment of patients with visual impairment due to diabetic macular oedema. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of aflibercept 8 mg would be acceptable if it were cost-minimised to the lowest cost PBS-listed anti-VEGF treatment for the same indication. The PBAC considered that, on balance, a 1:1 dosing relativity with faricimab was reasonable and noted the dosing relativity previously accepted for aflibercept 2 mg:ranibizumab was 1:1. The PBAC supported a 2-year time horizon for the cost-minimisation calculation and considered the equi-effective doses to be 12.91 doses of aflibercept 8 mg/faricimab and 11.65 doses of aflibercept 2 mg/ranibizumab.</p>
<p align="center">AFLIBERCEPT</p> <p>Solution for intravitreal injection 11.34 mg in 100 microlitres (114.3 mg per mL)</p> <p align="center">Eylea®</p> <p align="center">BAYER AUSTRALIA LTD</p> <p align="center">(New PBS listing)</p>	<p align="center">Subfoveal choroidal neovascularisation (CNV) secondary to age-related macular degeneration (nAMD)</p>	<p align="center">To request a General Schedule Authority Required (Written) listing for the treatment of visual impairment caused by CNV secondary to nAMD.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the Authority Required listing of aflibercept 8 mg for the treatment of patients with visual impairment caused by CNV secondary to nAMD. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of aflibercept 8 mg would be acceptable if it were cost-minimised to the lowest cost PBS-listed anti-VEGF treatment for the same indication. The PBAC considered that, on balance, a 1:1 dosing relativity with faricimab was reasonable and noted the dosing relativity previously accepted for aflibercept 2 mg:ranibizumab was 1:1. The PBAC supported a 2-year time horizon for the cost-minimisation calculation and considered the equi-effective doses to be 11.50 doses of aflibercept 8mg/faricimab and 14.00 doses of aflibercept 2 mg/ranibizumab.</p>

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<p style="text-align: center;">FOSLEVODOPA WITH FOSCARBIDOPA</p> <p>Solution for subcutaneous infusion foslevodopa 2400 mg with foscarnidopa 120 mg in 10 mL</p> <p style="text-align: center;">Vyalev®</p> <p style="text-align: center;">ABBVIE PTY LTD</p> <p style="text-align: center;">(New PBS listing)</p>	<p style="text-align: center;">Advanced Parkinson's Disease</p>	<p style="text-align: center;">To request a General Schedule and Section 100 (Highly Specialised Drugs Program) Authority Required (STEAMLINED) listing for the treatment of advanced Parkinson's disease with severe disabling motor fluctuations not adequately controlled by oral therapy.</p>	<p>Not Recommended</p>	<p>The PBAC did not recommend the listing of foslevodopa/foscarnidopa (FosLD/FosCD) for the treatment of advanced Parkinson's disease in patients with severe disabling motor fluctuations not adequately controlled by oral therapy. In not recommending the listing, the PBAC considered further data and analyses were required to address concerns regarding the impact of discontinuations in the pivotal FosLD/FosCD (M15-736) trial on both the estimated efficacy for FosLD/FosCD and the indirect comparison with levodopa/carbidopa intestinal gel (LCIG). The PBAC considered a number of inputs for the cost minimisation to be uncertain, which likely resulted in the cost of FosLD/FosCD per patient being more than for LCIG, and noted the CMA did not include the costs associated with treating adverse events. The PBAC agreed with the submission that as a subcutaneous treatment option, the use of FosLD/FosCD in practice was likely to be greater than the current intestinal gel option and considered that a Risk Sharing Arrangement (RSA) would be appropriate for the listing. The PBAC considered the outstanding issues could be addressed in an early re-entry submission.</p> <p><u>Sponsor's comment:</u></p> <p>AbbVie is disappointed that the PBAC did not recommend foslevodopa and foscarnidopa (Vyalev) given the high clinical need for an alternative treatment option in advanced Parkinson's disease. AbbVie acknowledges the option of early re-entry and will continue to work with the PBAC and the Department of Health and Aged Care to ensure funded availability as soon as possible.</p>

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<p style="text-align: center;">RESPIRATORY SYNCYTIAL VIRUS VACCINE</p> <p style="text-align: center;">Injection (0.5 mL)</p> <p style="text-align: center;">Abrysvo®</p> <p style="text-align: center;">PFIZER AUSTRALIA PTY LTD</p> <p style="text-align: center;">(New NIP listing)</p>	<p style="text-align: center;">Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)</p>	<p style="text-align: center;">A resubmission requesting a National Immunisation Program (NIP) listing for recombinant syncytial pre-fusion F protein vaccine for the prevention of lower respiratory tract illness caused by RSV in infants from birth through to 6 months of age by the active immunisation of pregnant women.</p>	<p>Recommended</p>	<p>The PBAC recommended that respiratory syncytial virus vaccine (Abrysvo®, RSVpreF) be a designated vaccine for the purposes of the <i>National Health Act 1953</i> for the prevention of lower respiratory tract illness (LRTI) caused by RSV in infants from birth through 6 months of age by active immunisation of pregnant women. The PBAC considered that the vaccine was superior to no vaccine in terms of effectiveness, based on the reduced risk of medically attended-lower respiratory tract illness (MA-LRTI) and severe MA-LRTI due to RSV among infants during the first 6 months of life. The PBAC considered that the adverse event profile of RSVpreF was acceptable compared to placebo. The PBAC noted that the resubmission had offered a lower price compared with the price considered by the PBAC in March 2024, and had accepted most of its advice arising from that meeting. However, the resubmission had not accepted the PBAC’s advice regarding the estimates of vaccine efficacy (VE) to be applied in the economic evaluation. The PBAC maintained its advice from the March 2024 meeting, that clinical trial data with 12 months of follow-up be used to inform the VE, rather than with 6 months of follow-up as proposed by the resubmission. The PBAC noted using clinical trial data with 12 months of follow-up to inform the VE resulted in an ICER that was unacceptably high. On this basis, the PBAC considered that a price reduction would be required to ensure the vaccine is cost-effective in the proposed circumstances of use.</p>

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Non-submission items

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<p>LISDEXAMFETAMINE AND METHYLPHENIDATE</p> <p>All forms and strengths</p> <p>Various brands</p> <p>Various sponsors</p> <p>(Change to listing)</p>	<p>Attention deficit hyperactivity disorder (ADHD)</p>	<p>To seek changes to the listings of lisdexamfetamine and methylphenidate to remove ambiguity about the intended cost-effective population.</p>	<p>Recommended</p>	<p>The PBAC recommended amending the current PBS listings of lisdexamfetamine and methylphenidate as follows:</p> <ul style="list-style-type: none"> • lisdexamfetamine (Vyvanse) and methylphenidate (Ritalin LA, Rubifen LA): to amend the paediatric restriction criteria wording to clarify that access is for patients up to turning 18 years of age; • lisdexamfetamine (Vyvanse) and methylphenidate (Ritalin LA, Rubifen LA, Concerta, Methylphenidate XR ARX, Methylphenidate XR Teva): to amend the restriction criteria wording to clarify that limits to maximum daily dose and once daily dosing apply to PBS subsidised supply; • methylphenidate (Concerta, Methylphenidate XR ARX, Methylphenidate XR Teva): to include administrative advice regarding access via Service Australia's Online PBS Authorities system.
<p>MIGALASTAT</p> <p>Capsule containing migalastat hydrochloride 150 mg</p> <p>Galafold®</p> <p>AMICUS THERAPEUTICS PTY LTD</p> <p>(Matters arising)</p>	<p>Fabry disease</p>	<p>To reconsider the March 2024 recommendation in relation to:</p> <p>(i) wording of the cardiac criterion</p> <p>(ii) rebate over the expenditure caps.</p>	<p>Recommended</p>	<p>The PBAC recommended amending the cardiac restriction criterion it recommended in March 2024 to include late gadolinium enhancement or low T1 changes on cardiac magnetic resonance imaging. The PBAC noted this requested change to the restriction was consistent with the Fabry Australia Treatment Review White Paper (now published as Nicholls 2024). The PBAC considered this amendment was clinically appropriate and it was unlikely to increase the number of eligible patients. The PBAC reiterated its previous consideration that the number of eligible patients with evidence of organ involvement/injury was high but reasonable. However, the PBAC considered it would be reasonable to amend the rebate previously recommended for any cost over the expenditure caps to share any residual uncertainty regarding the eligible patient numbers, particularly the uncertainty associated with the transition from the Life Saving Drugs Program to the PBS.</p>

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<p align="center">SOMATROPIN</p> <p>Various forms and strengths</p> <p>Various brands</p> <p>Various sponsors</p> <p>(Correspondence)</p>	<p align="center">Late onset growth hormone (GH) deficiency</p>	<p align="center">Correspondence from the Endocrine Society of Australia to seek PBAC advice on amending the circumstances under which somatropin is listed on the PBS for adults with late onset GH deficiency.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended amending the circumstances under which somatropin is listed under the Section 100 (GH) instrument for the treatment of late onset GH deficiency to enable adults with established hypothalamic-pituitary disease to be eligible for access to somatropin without the requirement to undergo dynamic testing (e.g. insulin tolerance test or glucagon provocative test). The PBAC considered the changes to the restrictions would not result in an increased cost to Government as the proposed subset of patients are within the intended population of the restrictions and are currently accessing treatment under the existing restrictions.</p> <p>The PBAC considered that the amendment to the PBS restrictions would improve patient experience by aligning with current clinical guidelines and practice to remove these additional testing requirements and improve patient access by avoiding delays in initiation of treatment while awaiting pathology results.</p>
<p>REVIEW OF ITEMS FOR NURSE PRACTITIONER AND ENDORSED MIDWIFE PRESCRIBING ON THE PHARMACEUTICAL BENEFITS SCHEME</p> <p>Various forms and strengths</p> <p>Various brands</p> <p>Various sponsors</p> <p>(Other matters)</p>	<p align="center">Various medicines</p>	<p align="center">To provide the PBAC with an update on the review of PBS prescribing by nurse practitioners and endorsed midwives.</p>	<p align="center">Advice provided</p>	<p>The PBAC noted an update on the review of PBS prescribing by authorised nurse practitioners and endorsed midwives, including the public consultation survey undertaken by the Department of Health and Aged Care in March 2024. The PBAC acknowledged the Department is working through the high volume of survey responses received and medicines identified as requiring PBAC consideration in this review. The PBAC agreed to review and provide its advice on relevant PBS listings in tranches. The PBAC provided advice to the Department on reviewing the administrative notes on some PBS items for prescribing by nurse practitioners in the form of a 'Shared Care Model' (SCM) note and a 'Continuing Therapy Only' note. The PBAC noted the Government's intent to remove the legislated requirement for nurse practitioners and endorsed midwives to have specified collaborative arrangements in place with medical practitioners for the purposes of PBS prescribing. The PBAC noted that the SCM note includes a requirement for a 'formalised arrangement' to be in place between a nurse practitioner and medical practitioner. The PBAC agreed to provide its recommendations on any changes to PBS items with the SCM note at a subsequent meeting.</p>

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<p align="center">UPDATE ON POST-MARKET REVIEW (PMR) WORKPLAN</p> <p align="center">DEPARTMENT OF HEALTH AND AGED CARE</p> <p align="center">(Other matters)</p>	<p align="center">N/A</p>	<p align="center">To provide the PBAC with an update on the status of current Post-market Review (PMR) research projects.</p>	<p align="center">Noted</p>	<p>The PBAC recalled its endorsement of a revised PMR Framework in December 2023, which was subsequently approved by the Minister for Health and Aged Care and published on the PBS website in January 2024. The PMR noted that no PMRs are currently underway, but future topics for PMRs could be requested by the Minister, identified by the PBAC or its subcommittees, or suggested by stakeholders by writing to the PBAC or the PMR section. The PBAC noted that the PMR framework provides for preliminary research projects to be undertaken by the Department to inform its consideration of potential PMR topics, with the aim of ensuring the ongoing quality and cost-effective use of PBS-listed medicines.</p> <p>The PBAC noted the status of the research projects outlined in the PMR work plan, which will be published on the PBS website. This included a utilisation analysis of heart failure medications, a utilisation analysis of antihypertensives, and a systematic literature review on the efficacy and safety of preservative-free compared with preservative-containing ocular lubricants for the treatment of severe dry eye. The PBAC noted that restriction changes for type 2 diabetes medicines would be implemented on 1 June 2024, as recommended by the PBAC in March 2023, July 2023, and March 2024.</p>
<p align="center">UPDATES TO THE RESTRICTIONS FOR EZETIMIBE AND ITS FIXED-DOSE COMBINATIONS (FDCs)</p> <p align="center">Various</p> <p align="center">(PBS review)</p>	<p align="center">Hypercholesterolaemia</p>	<p align="center">To seek PBAC advice on whether the PBS restrictions for ezetimibe and ezetimibe fixed dose combinations (FDCs) should be simplified.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended that the PBS restriction level for ezetimibe and ezetimibe + HMG-CoA reductase inhibitor (statin) FDCs be changed from Authority Required (STREAMLINED) to Unrestricted benefit listings. The PBAC considered that the utilisation of ezetimibe and its FDCs had stabilised and noted that expenditure had reduced significantly since 2014. The PBAC considered that the clinical place of ezetimibe and its FDCs was well established and that the change to an Unrestricted PBS listing was unlikely to result in increased utilisation or expenditure.</p> <p>The PBAC noted that sponsors would be consulted on the recommended restriction changes prior to implementation, and that this work would be included on the published PMR Work Plan.</p>

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<p>PBS RESTRICTIONS FOR COVID-19 TREATMENTS AND LISTINGS WITH RESPIRATORY PATHOGEN DETECTION TESTING REQUIREMENTS</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p>Pfizer Australia Pty Ltd</p> <p>(Correspondence)</p>	<p>SARS-CoV-2 infection Medicines with PBS requirements for respiratory pathogen detection testing</p>	<p>Correspondence from the Medical Services Advisory Committee (MSAC) to seek PBAC consideration of updating the PBS restriction criteria for respiratory pathogen testing in COVID-19 treatment listings</p>	<p align="center">Recommended</p>	<p>The Pharmaceutical Benefits Advisory Committee (PBAC) recommended amending the PBS clinical criteria for the COVID-19 medicines, molnupiravir (Lagevrio®) and nirmatrelvir and ritonavir (Paxlovid®) to be method-agnostic with regards to nucleic acid testing for respiratory pathogen detection. The PBAC noted that the MSAC supported the creation of two new Medicare Benefits Schedule (MBS) items for nucleic acid testing for 4 and 5 or more respiratory pathogens, and that these items descriptors stated 'respiratory pathogen nucleic acid testing' and were method agnostic. The PBAC considered that it was appropriate to align the respiratory pathogen testing requirements for Lagevrio and Paxlovid on the PBS with the MBS item requirements. The PBAC noted that no other PBS-listed items would be affected by the new MBS items for nucleic acid testing for respiratory pathogens.</p>

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Resubmission pathways

<p>*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:</p>	
Standard re-entry	<p>The Standard Re-entry Pathway is the default pathway for resubmissions and also applies where:</p> <ul style="list-style-type: none"> • 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	<p>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.</p>
Early resolution pathway	<p>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:</p> <ul style="list-style-type: none"> • 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. <p>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.</p>
Facilitated resolution pathway	<p>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.</p>