

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES  
MAY 2022 PBAC INTRACYCLE MEETING**

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

*Submission items*

<b>DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION</b>	<b>DRUG TYPE AND USE</b>	<b>LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION</b>	<b>PBAC OUTCOME</b>	
<p>APREMILAST</p> <p>Tablet 30 mg Pack containing 4 tablets 10 mg, 4 tablets 20 mg and 19 tablets 30 mg</p> <p>Otezla®</p> <p>Amgen Australia Pty Limited</p> <p>(Change to PBS listing)</p>	<p>Severe chronic plaque psoriasis</p>	<p>To review the treatment criteria to allow general practitioners to prescribe maintenance treatment.</p>	<p>Recommended</p>	<p>The PBAC recommended amendments to the treatment criteria for apremilast to allow accredited dermatology registrars to initiate treatment in consultation with a dermatologist and to allow general practitioners to prescribe maintenance treatment in consultation with a dermatologist or accredited dermatology registrar. The PBAC advised that the changes to the initial treatment criteria for apremilast to include dermatology registrar prescribing should flow-on to ciclosporin for the treatment of severe psoriasis.</p>
<p>BUROSUMAB</p> <p>Injection 10 mg in 1 mL, injection 20 mg in 1 mL, injection 30 mg in 1 mL</p> <p>Crysvita®</p> <p>Kyowa Kirin Australia Pty Ltd</p> <p>(New PBS listing)</p>	<p>X-linked hypophosphataemia (XLH)</p>	<p>Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of XLH.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of burosomab for the treatment of patients with XLH. The PBAC noted the high clinical need and previous strong consumer support for the listing of treatments for this condition. The PBAC considered that the incremental cost-effectiveness ratios for both the paediatric and adult populations were acceptable at the proposed price and that the proposed risk sharing arrangement was adequate to manage the risks associated with the uncertainties relating to the estimated financial impact to the PBS.</p>
<p>DARATUMUMAB</p> <p>Solution for subcutaneous injection 1,800 mg in 15 mL vial</p> <p>Darzalex SC®</p> <p>Janssen-Cilag Pty Ltd</p> <p>(New PBS listing)</p>	<p>Amyloid light-chain (AL) amyloidosis</p>	<p>Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (Telephone) listing, for use in combination with cyclophosphamide, bortezomib and dexamethasone (CyBorD), for the treatment of patients with newly diagnosed AL amyloidosis.</p>	<p>Recommended</p>	<p>The PBAC recommended daratumumab subcutaneous (SC) for use in combination with CyBorD for the treatment of patients with newly diagnosed systemic AL amyloidosis. The PBAC recognised that there are no treatments on the PBS available specifically for this condition, and it considered that the addition of daratumumab SC with CyBorD offered a high added therapeutic value. The PBAC considered that the revised economic analysis which included more conservative assumptions, and a risk sharing arrangement based on reduced financial estimates which also accounted for the overlap between patients with AL amyloidosis and multiple myeloma, were acceptable.</p>

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<p>DULAGLUTIDE</p> <p>Injection 3 mg in 0.5 mL single dose pre-filled pen Injection 4.5 mg in 0.5 mL single dose pre-filled pen</p> <p>Trulicity®</p> <p>Eli Lilly Australia Pty Ltd</p> <p>(Matters outstanding)</p>	<p>Type 2 diabetes mellitus (T2DM)</p>	<p>To request General Schedule Authority Required (STREAMLINED) listings of two new forms for the treatment of patients with T2DM who require treatment intensification to achieve glycaemic targets, as dual therapy in combination with metformin.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of dulaglutide 3 mg and 4.5 mg for the treatment of T2DM in combination with metformin in patients who are contraindicated or intolerant to a combination of metformin and a sulfonylurea. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of dulaglutide 3 mg and 4.5 mg would be acceptable if it were cost-minimised against dulaglutide 1.5 mg. As such, the PBAC recommended that the PBS listing for dulaglutide 3 mg and 4.5 mg should be the same as the dulaglutide 1.5 mg listing for use in combination with metformin.</p>
<p>FARICIMAB</p> <p>Solution for intravitreal injection 28.8 mg in 0.24 mL</p> <p>Vabysmo®</p> <p>Roche Products Pty Ltd</p> <p>(New PBS listing)</p>	<p>Diabetic macular oedema (DMO)</p>	<p>To request a General Schedule Authority Required (Written) listing for the treatment of DMO.</p>	<p>Recommended</p>	<p>The PBAC recommended the Authority Required listing of faricimab for the treatment of patients with visual impairment due to DMO. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of faricimab would be acceptable if it were cost-minimised to PBS-listed anti-VEGF treatments such as aflibercept and ranibizumab for the same indication.</p> <p>The PBAC supported a 2-year time horizon for the cost-minimisation calculation, and considered the equi-effective doses to be:</p> <ul style="list-style-type: none"> <li>• Year 1: 8.23 doses of faricimab annually to 6.38 doses of aflibercept 2 mg annually</li> <li>• Year 2: 4.68 doses of faricimab annually to 5.27 doses of aflibercept 2 mg annually.</li> </ul> <p>The PBAC considered that, based on the clinical evidence provided, the claim of non-inferior comparative effectiveness and safety of faricimab compared to aflibercept was acceptable. The PBAC considered the proposed cost savings with listing faricimab to be overestimated, in particular noting that the cost savings estimated in the submission depend on the assumed dose frequencies, which may not be realised if dose frequencies differ in clinical practice. The PBAC considered that there should be no extra cost to Government given the PBAC's acceptance of the faricimab administration frequency, which was based on an analysis of the faricimab administration frequency in the RHINE/YOSEMITE trials and of the aflibercept administration frequency using PBS data for aflibercept supply.</p>

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<p>FARICIMAB</p> <p>Solution for intravitreal injection 28.8 mg in 0.24 mL</p> <p>Vabysmo®</p> <p>Roche Products Pty Ltd</p> <p>(New PBS listing)</p>	<p>Neovascular (wet) age-related macular degeneration (nAMD)</p>	<p>To request a General Schedule Authority Required (Written) listing for the treatment of nAMD.</p>	<p>Recommended</p>	<p>The PBAC recommended the Authority Required listing of faricimab for the treatment of nAMD. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of faricimab would be acceptable if it were cost-minimised to PBS-listed anti-VEGF treatments such as aflibercept and ranibizumab for the same indication.</p> <p>The PBAC supported a 2-year time horizon for the cost-minimisation calculation, and considered the equi-effective doses to be:</p> <ul style="list-style-type: none"> <li>• Year 1: 7.20 doses of faricimab annually to 7.69 doses of aflibercept 2 mg annually</li> <li>• Year 2: 4.30 doses of faricimab annually to 6.31 doses of aflibercept 2 mg annually.</li> </ul> <p>The PBAC considered that, based on the clinical evidence provided, the claim of non-inferior comparative effectiveness and safety of faricimab compared to aflibercept was acceptable. The PBAC considered that there should be no extra cost to Government given the PBAC's acceptance of the faricimab administration frequency, based on an analysis of the faricimab administration frequency in the first year of treatment, which was derived from the average doses in the first 48 weeks of treatment in the TENAYA and LUCERNE trials (6.4 mean administrations through to Week 48, average treatment duration of 46.2 weeks) apportioned to a 52 week estimate, and the aflibercept administration frequency using PBS data for aflibercept supply.</p>
<p>MODAFINIL</p> <p>Tablet 100 mg</p> <p>ARMODAFINIL</p> <p>Tablet 50 mg Tablet 150 mg Tablet 250 mg</p> <p>Multiple brands and sponsors</p> <p>(Change to PBS listing)</p>	<p>Narcolepsy</p>	<p>To request that the PBS listings for modafinil and armodafinil be changed to first line treatment of narcolepsy in line with current clinical guidelines.</p>	<p>Recommended</p>	<p>The PBAC recommended extending the listing of modafinil and armodafinil as first line treatments for patients with narcolepsy on a cost-minimisation basis to dexamfetamine. The PBAC considered that there was no clinical evidence to suggest that modafinil or armodafinil have superior comparative effectiveness or safety compared to dexamfetamine, and therefore considered that neither armodafinil nor modafinil should be more costly than dexamfetamine if they are to be listed for the first-line treatment of narcolepsy. The PBAC considered that the equi-effective doses are dexamfetamine 60 mg ≡ modafinil 400 mg ≡ armodafinil 250 mg.</p>

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<p>PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p>Keytruda®</p> <p>Merck Sharp &amp; Dohme (Australia) Pty Ltd</p> <p>(Matters outstanding)</p>	<p>Gastro-oesophageal cancers</p>	<p>To consider additional information provided by the sponsor in relation to the deferral of the decision to recommend listing of pembrolizumab on the PBS for gastro-oesophageal cancers.</p>	<p>Recommended</p>	<p>The PBAC recommended the listing of pembrolizumab in combination with chemotherapy for the first line treatment of advanced or metastatic gastro-oesophageal cancers as defined by the specific tumour types included in the approved Therapeutic Goods Administration indications. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of pembrolizumab (as a first line treatment) would be acceptable at the same or lower cost per 3 weekly treatment cycle as for nivolumab (as a first line treatment) for gastro-oesophageal cancers. The PBAC considered it was appropriate for pembrolizumab to be included in the risk share arrangement recommended for nivolumab, with the expenditure caps increased to account for the expected additional use in the first line treatment of oesophageal squamous cell carcinoma.</p>
<p>PREGABALIN</p> <p>Tablet 82.5 mg Tablet 165 mg Tablet 330 mg</p> <p>Lyrica® CR</p> <p>Upjohn Australia Pty Ltd</p> <p>(Matters outstanding)</p>	<p>Neuropathic pain</p>	<p>To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of neuropathic pain in adults, where this condition is refractory to treatment with other drugs.</p> <p>The PBAC deferred making a recommendation at its November 2021 meeting and requested further information on the use of pregabalin.</p>	<p>Not recommended</p>	<p>The PBAC did not recommend the listing of a controlled released (CR) formulation of pregabalin (pregabalin CR) for the treatment of neuropathic pain. The PBAC noted that the input from patients and stakeholders outlined the risks associated with pregabalin use and did not identify an unmet need in the current neuropathic pain population, and therefore considered that there was no established clinical need for listing a CR formulation. Furthermore, given the known adverse event profile of pregabalin, the PBAC considered that the additional quality use of medicines (QUM) concerns such as patient confusion and prescribing errors (previously noted at its November 2021 meeting) had the potential to increase the risk of adverse events.</p> <p>The PBAC considered that the concomitant use of pregabalin with other drugs was a potential concern, noting that most pregabalin toxicity is associated with its use with opioids, benzodiazepines, alcohol or illegal drugs. The PBAC noted that the Drug Utilisation Sub Committee (DUSC) analysis reported that a high proportion of younger patients were identified as being supplied pregabalin with an opioid or benzodiazepine.</p> <p>The PBAC noted that the DUSC analysis reported a larger number of PBS pregabalin scripts being prescribed by rheumatologists and psychiatrists, which may suggest use outside the PBS restrictions. The PBAC considered that the potential for increased misuse and overdosing with a CR formulation of pregabalin could not be ruled out.</p> <p><u>Sponsor Comment:</u> The sponsor had no comment.</p>

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<p>PREGABALIN</p> <p>Oral solution 20 mg per mL, 473 mL</p> <p>Pregabalin-AFT®</p> <p>AFT Pharmaceuticals (Au) Pty Ltd</p> <p>(Matters outstanding)</p>	<p>Neuropathic pain</p>	<p>To request an Authority Required (streamlined) listing of pregabalin solution under the same circumstances as the existing listed pregabalin.</p> <p>The PBAC deferred making a recommendation at its November 2021 meeting and requested further information on the use of pregabalin.</p>	<p>Not recommended</p>	<p>The PBAC did not recommend the listing of pregabalin 20 mg per mL oral liquid (Pregabalin-AFT) for the treatment of neuropathic pain. The PBAC noted that the input from clinical organisations outlined the risks associated with pregabalin use and did not identify an unmet need in the current neuropathic pain population, and therefore considered that there was no established clinical need for listing an oral liquid. Furthermore, given the known adverse event profile of pregabalin, the PBAC considered that the additional quality use of medicines (QUM) concerns such as patient confusion and prescribing errors (previously noted at its November 2021 meeting) had the potential to increase the risk of adverse events.</p> <p>The PBAC considered that the concomitant use of pregabalin with other drugs was a potential concern, noting that most pregabalin toxicity is associated with its use with opioids, benzodiazepines, alcohol or illegal drugs. The PBAC noted that the Drug Utilisation Sub Committee (DUSC) analysis reported that a high proportion of younger patients were identified as being supplied pregabalin with an opioid or benzodiazepine.</p> <p>The PBAC noted that the DUSC analysis reported a larger number of PBS pregabalin scripts being prescribed by rheumatologists and psychiatrists, which may indicate use outside the PBS restrictions. The PBAC considered that the potential for increased misuse and overdosing with an oral liquid formulation of pregabalin could not be ruled out.</p> <p><u>Sponsor Comment:</u> The sponsor had no comment.</p>
<p>TRIENTINE</p> <p>Tablet 150 mg (as tetrahydrochloride)</p> <p>Cuprior®</p> <p>Orphalan</p> <p>(Matters arising)</p>	<p>Wilson disease</p>	<p>Resubmission to request a General Schedule Authority Required listing for the treatment of patients with Wilson disease who are intolerant to penicillamine.</p>	<p>Recommended</p>	<p>The PBAC recommended the PBS listing of trientine tetrahydrochloride (4HCl) for the treatment of patients with Wilson disease who are intolerant to penicillamine/D-penicillamine. The PBAC noted that trientine dihydrochloride (2HCl) was a near market comparator and considered trientine 4HCl and trientine 2HCl to be non-inferior in terms of efficacy and safety. The PBAC considered that the cost effectiveness of trientine 4HCl could be brought into an acceptable range with a reduced price.</p>
<p>TRIENTINE</p> <p>Capsule 250 mg (as dihydrochloride)</p>	<p>Wilson disease</p>	<p>Resubmission to request a General Schedule Authority Required listing for the treatment of patients with</p>	<p>Recommended</p>	<p>The PBAC recommended the PBS listing of trientine dihydrochloride for the treatment of patients with Wilson disease who are intolerant to penicillamine/D-penicillamine. The PBAC considered that the price offered in the revised pricing proposal was acceptable.</p>

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Waymade®  Clinect Pty Ltd  (Matters arising)		Wilson disease who are intolerant to penicillamine.		

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*Non-submission items*

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<p>MELANOMA SEQUENCING OF TREATMENT</p> <p>Various brands</p> <p>Various sponsors</p> <p>(Change to PBS listing)</p>	<p>Immunotherapies and BRAF inhibitors in metastatic melanoma</p>	<p>To review the sequencing of immunotherapies and BRAF inhibitors in metastatic melanoma.</p>	<p align="center">Noted</p>	<p>The PBAC noted that the sponsor of nivolumab with ipilimumab, Bristol-Myers Squibb, provided the requested data relating to the DREAMSeq and SECOMBIT trials regarding the sequencing of immunotherapies and BRAF-inhibitors in the treatment of BRAF 600 mutant positive (BRAF+) metastatic melanoma.</p> <p>The PBAC noted that the recommendation at the November 2019 meeting to expand the restrictions for immunotherapies and BRAF-inhibitors to allow clinicians to choose the optimal sequencing of therapy based on their patient's individual circumstances was supported by the new trial data provided.</p>

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<p>NICOTINE REPLACEMENT THERAPY</p> <p>Various forms</p> <p>Various sponsors</p> <p>BUPROPION</p> <p>VARENICLINE</p> <p>All listed brands</p> <p>Various sponsors</p> <p>(Post-market Review)</p>	<p style="text-align: center;">Smoking cessation therapy for nicotine dependence</p>	<p>To consider the findings of the Post-market Review (PMR) of medicines for smoking cessation.</p> <p>To consider the findings from the cost-effectiveness review (CER) of combinations of smoking cessation medicines recommended by the Economics Sub Committee (ESC) of the PBAC following consideration of the PMR in June 2021.</p> <p><a href="https://www.pbs.gov.au/info/reviews/post-market-review-of-medicines-for-smoking-cessation">https://www.pbs.gov.au/info/reviews/post-market-review-of-medicines-for-smoking-cessation</a>.</p>	<p style="text-align: center;">Recommended</p>	<p>The PBAC noted stakeholder submissions to the Review, sponsor pre-sub-committee responses, one pre-PBAC response, and the ESC and the Drug Utilisation Sub Committee (DUSC) advice.</p> <p>The PBAC considered both the PMR report and the ‘CER of Combinations of Smoking Cessation Medicines’, and overall accepted the key findings.</p> <p>The PBAC considered the six options proposed by the Review Reference Group and made the following comments and recommendations.</p> <p>The PBAC recommended allowing an additional 12 weeks of PBS-subsidised nicotine replacement therapy (NRT) in a 12-month period for:</p> <ul style="list-style-type: none"> <li>• the re-treatment of patients who had an unsuccessful quit attempt.</li> <li>• patients who have ceased smoking during the initial 12 weeks of therapy to prevent relapse.</li> </ul> <p>The PBAC recommended allowing combinations of an NRT patch with short acting formulations to be used concomitantly on the PBS; but where combination NRT is prescribed, subsidy be limited to up to two different forms.</p> <p>The PBAC did not recommend allowing combinations of PBS-subsidised NRT patch formulations to facilitate double patching. The PBAC requested that the Department of Health explore options for the PBS subsidy of double patching via an authority required level of restriction to be considered by the PBAC at a later date.</p> <p>The PBAC considered the incremental cost-effectiveness ratios (ICERs) for varenicline (VAR) <i>versus</i> NRT and combination VAR+NRT <i>versus</i> VAR and NRT as monotherapy high, and therefore did not recommend subsidising VAR+NRT on the PBS. The PBAC requested that the Department consider the impact of different pricing options to reduce the ICERs for VAR <i>versus</i> NRT and VAR+NRT <i>versus</i> VAR and bring any additional analyses and estimates of PBS expenditure to the PBAC once supply of the originator brand of VAR is re-instated.</p> <p>The PBAC supported the prospect of an education campaign targeting prescribers to raise awareness of the improved effectiveness of smoking cessation pharmacotherapies when provided in combination with comprehensive support and counselling.</p> <p>The PBAC advised that it would remain open to submissions from sponsors to list inhaler and mouth spray NRT formulations on a cost-minimisation basis to the currently listed NRT gum and lozenge products.</p> <p>The PBAC requested follow-up with Queensland Quitline regarding the evaluation of the ‘Intensive Quit Support Program’ to explore if there are other</p>
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				effective ways of providing access to government funded NRT in addition to the current PBS and Section 100 arrangements. The PBAC noted that access to NRT should not be contingent on specific or state-based government programs and considered that whilst the program evaluation by Queensland Health may be positive, it should not limit other ways of accessing NRT for consumers.
<p>ROMIPLOSTIM</p> <p>Powder for injection 375 micrograms Powder for injection 625 micrograms</p> <p>Nplate®</p> <p>Amgen Australia Pty Limited</p> <p>ELTROMBOPAG</p> <p>Tablet 25 mg (as olamine) Tablet 50 mg (as olamine)</p> <p>Revolade®</p> <p>Novartis Pharmaceuticals Australia Pty Limited</p> <p>(Change to PBS listing)</p>	<p>Thrombopoietin-receptor agonists (TPO-RAs) for primary immune thrombocytopenia (ITP)</p>	<p>To review the PBS restrictions for romiplostim and eltrombopag</p>	<p>Recommended</p>	<p>The PBAC recommended changes to the restrictions of romiplostim and eltrombopag on the PBS to align with current treatment guidelines. The PBAC recommended that:</p> <ul style="list-style-type: none"> <li>• switching between eltrombopag and romiplostim be allowed at any time and wording in the restriction about switching within 24 weeks be removed to mitigate any confusion among prescribers;</li> <li>• the requirement for prior splenectomy or contraindication to splenectomy use be removed;</li> <li>• children be included in the updated restrictions by removing age limits;</li> <li>• restrictions on platelet count specified in continuing treatment be removed, and treatment be allowed to continue if the patient can maintain a platelet count sufficient to prevent clinically significant bleeding;</li> <li>• the requirement to stipulate toxicity to corticosteroid and immunoglobulin be removed.</li> </ul>

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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>	
<b>Standard re-entry</b>	<p>The Standard Re-entry Pathway is the default pathway for resubmissions and also applies where:</p> <ul style="list-style-type: none"> <li>• an applicant chooses not to accept the PBAC nominated resubmission pathway; or</li> <li>• 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</li> <li>• an applicant decides to lodge later than the allowable timelines for the other pathways.</li> </ul>
<b>Early re-entry pathway</b>	<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 HATV for the proposed population. Applicants who accept this pathway are eligible for PBAC consideration at the immediate next meeting.</p>
<b>Early resolution pathway</b>	<p>For medicines or vaccines deemed by the PBAC to represent High Added Therapeutic Value (HATV) AND where the PBAC considers that the remaining issues could be easily resolved, including when:</p> <ul style="list-style-type: none"> <li>• 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</li> <li>• 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.</li> </ul> <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>
<b>Facilitated resolution pathway</b>	<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>