

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
DECEMBER 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">ADALIMUMAB</p> <p>Injection 20 mg in 0.2 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 80 mg in 0.8 mL pre-filled syringe Injection 80 mg in 0.8 mL pre-filled pen</p> <p align="center">Humira®</p> <p align="center">ABBVIE PTY LTD</p> <p align="center">(Matters Outstanding)</p>	<p align="center">Immune-mediated inflammatory diseases (IMID)</p>	<p>To consider:</p> <ul style="list-style-type: none"> - advice provided by clinical groups on the current Pharmaceutical Benefits Scheme (PBS) listings and eligibility criteria for adalimumab (Humira) and whether they reflect current evidence and practice in the management of paediatric immune-mediated inflammatory disease (IMID). - revised PBS listings of Humira proposed for paediatric IMID conditions for which there is evidence for the use of adalimumab. 	<p align="center">Recommended</p> <p>The PBAC recommended new listings for adalimumab for enthesitis/spondylitis related juvenile idiopathic arthritis (JIA) and chronic plaque psoriasis for paediatric patients, and recommended changes to the current listings for adalimumab for moderate to severe ulcerative colitis, severe Crohn disease and JIA for paediatric patients to reflect current evidence and practice in managing these conditions. The PBAC recalled that at its March 2024 meeting it had requested that advice be sought from clinical groups on the current PBS listings for adalimumab for paediatric patients, and that these listings be revised where necessary to reflect current evidence and practice based on this advice.</p> <p>The PBAC acknowledged the comprehensive advice received from clinical groups and clinicians from rheumatology, gastroenterology and dermatology specialties. Based on this advice, the PBAC recommended:</p>

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				<ul style="list-style-type: none">• new listings for adalimumab for enthesitis/spondylitis related JIA and chronic plaque psoriasis for paediatric patients.• the current PBS listings for adalimumab for moderate to severe ulcerative colitis and severe Crohn disease be changed to allow dose escalation and more flexible dosing.• the clinical criteria for adalimumab for paediatric patients with severe Crohn disease be changed to facilitate access to paediatric patients with extensive small bowel disease.• changes to the clinical criteria of the current PBS listings for adalimumab for severe active JIA to include a reduced methotrexate dose (15 mg per square metre) as prior treatment, and changes to the Prescribing Instructions for the criteria indicating failure to achieve an adequate response.• that subsequent continuing treatment PBS listings for adalimumab for all conditions for paediatric patients be changed to Authority Required (STREAMLINED) listings.
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			<p>The PBAC advised that these new and revised listings were acceptable at the current price.</p> <p>The PBAC recommended that, for current PBS listings for adalimumab where changes have been recommended, biosimilars currently listed for these indications be included in these revised listings. The PBAC recommended that, for the recommended new listings for adalimumab for paediatric patients, biosimilars that are TGA-registered for these indications be included in these listings.</p> <p>The PBAC recommended the changes to the severe Crohn disease listing to support access for patients who have extensive small bowel disease be flowed on to infliximab listings, and that the changes to the severe JIA listing be flowed on to etanercept, tocilizumab and tofacitinib listings, for the same indications for paediatric patients.</p>

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<p align="center">ARIPIRAZOLE</p> <p>I.M. injection (modified release) 720 mg in 2.4 mL pre-filled syringe, I.M. injection (modified release) 960 mg in 3.2 mL pre-filled syringe</p> <p align="center">Abilify Asimtufii®</p> <p>Lundbeck Australia Pty Ltd</p> <p align="center">(New listing)</p>	<p align="center">Long acting injectable form of aripiprazole for schizophrenia</p>	<p>To request a General Schedule Authority Required (STREAMLINED) listing for the maintenance treatment of schizophrenia.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the General Schedule, Authority Required (STREAMLINED) listing of aripiprazole once per 2-month injection (A2M) for the maintenance treatment of schizophrenia in patients who are stabilised on the once monthly formulation of aripiprazole (AOM). The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost effectiveness of A2M would be acceptable if it were cost minimised to AOM. The PBAC advised the equi-effective doses were: 1 injection of A2M 960 mg = 2 injections of AOM 400 mg; and 1 injection of A2M 720 mg = 2 injections of AOM 300 mg.</p>
<p align="center">ESKETAMINE</p> <p>Nasal spray solution 28 mg in 0.2 mL (2 actuations)</p> <p align="center">Spravato®</p> <p align="center">JANSSEN-CILAG PTY LTD</p> <p align="center">(Matters Outstanding)</p>	<p align="center">Treatment resistant depression</p>	<p>Deferred resubmission to request a Section 100 (Highly Specialised Drug Program) Authority Required (Telephone/Online) listing for the treatment of treatment resistant depression.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended the General Schedule and Section 100 (Highly Specialised Drugs Program – Public and Private Hospitals), authority required (telephone/online) listings of esketamine for treatment-resistant major depression in patients who have failed at least two prior oral anti-depressant drugs (OADs). In making this recommendation, the PBAC considered the additional changes to the restriction and financial estimates had adequately addressed its concerns raised at the July 2024 meeting. The PBAC noted consultation with the Royal Australian and</p>

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			<p>New Zealand College of Psychiatrists (RANZCP) led to a revised restriction that resulted in a more practical wording that supports use in the intended population. The PBAC considered the revised financial estimates provided a more reasonable basis for expenditure caps in the proposed Risk Sharing Arrangement. The PBAC reiterated its previous consideration that, given the uncertainty with how esketamine would be used in practice (particularly in terms of use beyond 12 months and the extent of retreatment), it was appropriate for utilisation to be monitored following the listing.</p>

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<p align="center">NIVOLUMAB</p> <p>Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL</p> <p align="center">Opdivo®</p> <p>BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD</p> <p>(Change to recommended listing)</p>	<p align="center">Non-small cell lung cancer (NSCLC)</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the perioperative treatment of NSCLC.</p>	<p align="center">Not recommended</p>	<p>The PBAC did not recommend the listing of nivolumab for the perioperative treatment of patients with resectable non-small cell lung cancer (NSCLC). The PBAC noted the perioperative use of nivolumab consisted of up to 4 doses prior to surgery in combination with chemotherapy (neoadjuvant treatment) and up to 12 months of treatment post-surgery as monotherapy (adjuvant treatment). The PBAC considered the appropriate comparator was neoadjuvant nivolumab (up to 3 doses prior to surgery in combination with chemotherapy) which is currently PBS listed. The PBAC considered that the additional doses of nivolumab in the adjuvant setting provided no clear clinical benefit compared to the comparator, however led to inferior safety and increased treatment burden for patients.</p> <p><u>Sponsor's Comment:</u></p> <p>Bristol-Myers Squibb Australia is extremely disappointed with the PBAC's not recommended outcome for this submission. BMSA has requested a post-PBAC meeting to look for a pathway forward for this important advance in treatment options for NSCLC patients.</p>

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Non-submission items

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<p>Utilisation analysis of antihypertensives</p> <p>Multiple sponsors (PBS review)</p>	<p>Hypertension</p>	<p>To provide the PBAC with a utilisation analysis of PBS- listed antihypertensives and to request that the PBAC consider the appropriateness of the current PBS restrictions for antihypertensive fixed dose combinations.</p>	<p>Recommended</p>	<p>The PBAC noted the report on antihypertensive utilisation through the PBS, which included a costing analysis and literature review. The PBAC recommended changing PBS restrictions for all antihypertensive dual therapy fixed dose combinations (FDCs) to unrestricted benefit listings. The PBAC recommended that 60-day prescription items should remain Restricted Benefit listings with a single clinical criterion requiring the patient's condition to be stable. The PBAC did not recommend any changes in PBS restrictions for triple therapy antihypertensive FDC's.</p> <p>The PBAC considered that the recommended restriction changes were likely to result in cost savings for the PBS and consumers. However, the PBAC considered the reported savings to be overestimated, as prescriber behaviour is likely to be guided by Australian clinical guidelines which do not currently contain a recommendation for initiating therapy with low dose dual antihypertensive therapy for most patients. The PBAC noted the Department's intention to revise the financial estimates, and that these would be brought back to the PBAC for consideration if a cost to the PBS was estimated.</p>

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				The PBAC highlighted several quality use of medicines issues identified in the report. The PBAC considered that it would be valuable to communicate the report findings to prescribers and consumers through relevant publications and peak bodies.
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Submission category types

Category 1	<p>A request for PBS or NIP listing of one or more of the following:</p> <ul style="list-style-type: none"> • 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	<p>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.</p>
Category 3	<p>Requests to change existing listings that do not change the population or costeffectiveness of the medicine or vaccine that do not meet the criteria for a Category 4 submission.</p>
Category 4	<p>A request for one or more of the following:</p> <ul style="list-style-type: none"> • Listing of a new pharmaceutical item of a listed medicine. • Consideration as an exempt item (Exempt item as per subsection 84AH of the <i>National Health Act 1953</i>). • 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	<p>Application is not in Categories 1, 2, 3 or 4 and requests for one or more of the following:</p> <ul style="list-style-type: none"> • 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.

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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 pathway resolution	<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>