PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
ITEMS CONSIDERED OUT OF SESSION BETWEEN ORDINARY MEETINGS (NOVEMBER 2025 – MARCH 2026)

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DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME	OUTCOME DETAILS
EDARAVONE Solution concentrate for I.V. infusion 30 mg in 20 mL Radicava® TEVA PHARMA AUSTRALIA PTY LTD Category 3 (Change to existing listing)	Amyotrophic lateral sclerosis (ALS)	To request a change to the existing listing of edaravone for the initial treatment of ALS, to allow initiation of treatment outside public or private hospital settings.	Recommended	The PBAC recommended adding a Section 100 (Highly Specialised Drugs (HSD) Community Access (CA)) listing of edaravone for initial treatment of amyotrophic lateral sclerosis, enabling community-based neurologists to initiate therapy. The PBAC considered this change to improve flexibility and equitable access for patients through community and hospital settings, particularly in rural and remote areas. The PBAC advised that the existing Section 100 HSD Public and Private hospital listings should be removed to avoid multiple PBS item codes, as the CA listing would continue to allow access in hospital settings. The PBAC recommended including a caution in the restriction regarding rare but clinically significant hypersensitivity risks, such as anaphylaxis and severe asthmatic episodes in susceptible individuals based on input received from clinical representative group for this treatment area. The PBAC considered that patients who commenced edaravone privately and met eligibility criteria at initiation (i.e., grandfathered patients) were intended to transition to PBS-subsidised therapy under the existing restrictions. The PBAC noted the sponsor had indicated the wording of the existing restrictions may require clarification to ensure the intent of the listing is clear for prescribers treating these patients. To support this, the PBAC advised amending the initial treatment criteria for clarity, enabling these patients to receive their first PBS supply under the initial treatment restriction and continue therapy under the continuing treatment restriction. The PBAC advised that prescribers should request quantities sufficient for one month per dispensing, aligned with the treatment cycle. The PBAC considered the financial impact of these changes to be minor as the patient groups were included in the original estimates, with only a small additional cost to the PBS due to differences in fees and mark-ups between the Section 100 HSD Public hospital and CA programs, which would be mitigated by the existing Risk Sharing Arrangement.

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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.

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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.