PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) INTRACYCLE MEETING AGENDA
September 2026 PBAC INTRACYCLE MEETING

Please note that items in this agenda are subject to change at short notice.

PBAC Intracycle meetings are held between the main PBAC meetings. Submission items considered by the PBAC at these meetings typically relate to matters arising from previous submissions (e.g. items deferred) but can also relate to new medicines or applications that were held over from a previous meeting.

Consumers have the opportunity to provide comments on new medicine submissions if this opportunity has not been provided previously. Consumer comments already received, such as those in relation to medicines subject to a resubmission or those that have been held over from a previous meeting have been retained and will be considered.

Please note that all items included in this agenda are subject to change at short notice and, when possible, an updated agenda will promptly be published.

Pharmaceutical benefits listed in the Schedule fall into three broad categories:
No restrictions – have no restrictions on their therapeutic uses;
Restricted Benefit – can only be prescribed for specific therapeutic uses (noted as Restricted benefit); and
Authority Required – Authority Required benefits fall into two categories:

- *Authority Required benefits* require prior approval from Services Australia or the DVA (noted as Authority Required)
- *Authority Required (STREAMLINED) benefits* do not require prior approval from Services Australia or the DVA but require the recording of a streamlined authority code (noted as Authority Required (STREAMLINED)).

Resubmissions are categorised broadly as Standard Re-entry Pathway, Early Resolution Pathway, Early Re-entry Pathway or Facilitated Resolution Pathway. Submission categories and resubmission pathways are outlined in the Procedure Guidance.

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Single drug/vaccine agenda items

Drug name, form(s), strength(s), tradename, sponsor, submission category and type, requested authority level and PBS schedule	**Drug Type and Use** (What is the drug used to treat?)	**Listing requested by Sponsor / Purpose of Submission** (Includes restriction wording. If restriction is lengthy it may be paraphrased.)
BUDESONIDE WITH GLYCOPYRRONIUM AND FORMOTEROL Pressurised inhalation containing budesonide 160 micrograms with glycopyrronium 14.4 micrograms and formoterol fumarate dihydrate 5 micrograms per dose, 120 doses Breztri Aerosphere® ASTRAZENECA PTY LTD Category 2 (New listing applications) Authority Required (STREAMLINED) PBS General Schedule	Severe asthma	To consider a request for listing of a new form of budesonide with glycopyrronium and formoterol for the maintenance treatment of severe asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta agonist (LABA) and an inhaled corticosteroid (ICS) who experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma.

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CEMIPLIMAB BROAD (MULTI-CANCER) LISTING Solution concentrate for I.V. infusion 350 mg in 7 mL Libtayo® MEDISON PHARMA AUSTRALIA PTY LIMITED (Other business)	Broad listing for immunotherapy-sensitive advanced or metastatic cancers	To consider and provide preliminary advice on a sponsor-provided summary of clinical evidence, intended to support a future submission requesting a broad PBS listing of cemiplimab for immunotherapy-sensitive advanced or metastatic cancers.
Durvalumab Broad (multi-cancer) Listing Solution concentrate for I.V. infusion 500 mg in 10 mL Imfinzi® AstraZeneca Pty Ltd (Other matters)	Broad listing for immunotherapy-sensitive advanced or metastatic cancers	To consider and provide preliminary advice on a sponsor-provided summary of clinical evidence, intended to support a future submission requesting a broad PBS listing of durvalumab for immunotherapy-sensitive advanced or metastatic cancers.

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GOSERELIN Subcutaneous implant (long acting) 10.8 mg (as acetate) in pre-filled injection syringe Zoladex® AstraZeneca Pty Ltd Category 2 (Change to existing listing) Restricted Benefit PBS General Schedule	HR+ Breast Cancer	To consider a request for the listing of goserelin subcutaneous implant (long acting) 10.8 mg (as acetate) in pre-filled injection syringe for the treatment of hormone receptor positive (HR+) breast cancer.

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NIRSEVIMAB Solution for injection 50 mg in 0.5 mL pre-filled syringe Solution for injection 100 mg in 1 mL pre-filled syringe Beyfortus™ SANOFI-AVENTIS AUSTRALIA PTY LTD Matters 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 RSV lower respiratory tract disease in neonates and infants born during or entering their first RSV season; and children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season
RESPIRATORY SYNCYTIAL VIRUS VACCINE Solution for injection 50 µg in 0.5 mL pre filled syringe mRESVIA® MODERNA AUSTRALIA PTY LTD Matters outstanding (New NIP listing)	Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)	To consider a request for 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.

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SARS-CoV-2 mRNA Injection (0.5mL) Spikevax® MODERNA AUSTRALIA PTY LTD Matters outstanding (New NIP listing) TO BE CONSIDERED AT A FUTURE PBAC MEETING	Prevention of coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2	To consider a request for National Immunisation Program (NIP) listing for the prevention of coronavirus disease 2019 (COVID-19) in individuals aged 18 years and older who have specific medical conditions that increase their risk of severe COVID-19.
TARLATAMAB Powder for injection 1mg, powder for injection 10 mg Imdelltra® AMGEN AUSTRALIA PTY LIMITED Early resolution (New PBS listing) Authority Required (STREAMLINED) PBS Section 100 (Efficient Funding of Chemotherapy)	Extensive-stage small cell lung cancer	To reconsider a request for listing tarlatamab for the second-line and subsequent treatment of adult patients with extensive-stage small cell lung cancer whose disease has progressed on or after platinum-based chemotherapy.

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Tislelizumab Broad (multi-cancer) Listing Solution concentrate for I.V. infusion 100 mg in 10 mL Tevimbra® BEONE MEDICINES AUS PTY LTD (Other matters)	Broad listing for immunotherapy-sensitive advanced or metastatic cancers	To consider and provide preliminary advice on a sponsor-provided summary of clinical evidence, intended to support a future submission requesting a broad PBS listing of tislelizumab for immunotherapy-sensitive advanced or metastatic cancers.

Other agenda items

AGENDA ITEM	PURPOSE OF AGENDA ITEM
Designated RN prescribing Internal submission (Change to existing listing)	To advise on which medicines within tranche 3 (body systems - Hormonal and systemic, Antiinfectives, Respiratory, Sensory, Musculo Skeletal, Various, and Antineoplastic) are suitable for prescribing by designated RN prescribers.

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AGENDA ITEM	PURPOSE OF AGENDA ITEM
Review of Attention Deficit Hyperactivity Disorder medicines - Tranche 1 (guanfacine and atomoxetine) (PBS review)	To: 1. Advise on the proposed amendments to the PBS listings atomoxetine and guanfacine to: • permit subsidised use in patients who have tolerated, but not adequately responded to, stimulant therapy; and • broaden prescriber eligibility beyond specialist-only initiation requirements. 2. Consider the estimated utilisation and financial impact associated with the proposed restriction changes. 3. Note pre-subcommittee and pre-PBAC responses and advice from the Drug Utilisation Sub-Committee (DUSC).
Review of PBS listings for low-cost antidepressants (PBS review)	To consider the estimated financial impact on the PBS of expanding multiple low-cost antidepressants from Restricted Benefit to Unrestricted Benefit listings and advise whether such expansion is appropriate.
Update on Post-market Review Workplan (PBS review)	To consider an update to the PMR workplan items progress and advise on next steps for those being progressed in short term (e.g. NACCHO items tamsulosin, rifampicin, ursodeoxycholic acid) as well as on any additional items to be added to the workplan or amended.

Version 2
Items added or amended
1. SARS-CoV-2 mRNA (Spikevax®) – To be considered at a future PBAC meeting