PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) INTRACYCLE MEETING AGENDA
MAY 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:
Unrestricted benefits – have no restrictions on their therapeutic uses;
Restricted benefits – can only be prescribed for specific therapeutic uses (noted as Restricted benefit); and
Authority required benefits – 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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Drug Name, form(s), strength(s), Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)	**Drug Type and Use** (What is the drug used to treat?)	**Listing requested by Sponsor / Purpose of Submission** (Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased.)
ADALIMUMAB and INFLIXIMAB ADALIMUMAB: Injection 20 mg in 0.2 mL pre-filled syringe Injection 20 mg in 0.4 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 40 mg in 0.8 mL pre-filled syringe Injection 40 mg in 0.8 mL pre-filled pen Injection 80 mg in 0.8 mL pre-filled syringe Injection 80 mg in 0.8 mL pre-filled pen INFLIXIMAB: Powder for I.V. infusion 100 mg Various brands and sponsors Internal submission (Change to existing listing)	Crohn disease (CD)	To consider amendments to the adalimumab and infliximab listings that permit dosing flexibility for the paediatric treatment of moderate to severe CD.
DESIGNATED REGISTERED NURSE PRESCRIBING (Internal submission - Other matters)	Not Applicable	To consider the Tranche 1 and Tranche 2 lists of medicines for designated registered nurse prescribing suitability.

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MIGALISTAT Capsule containing migalastat hydrochloride 150 mg Galafold® AMICUS THERAPEUTICS PTY LTD Matter arising from the minutes (Pricing matter)	Fabry Disease	To confirm the approach for adjusting the risk-sharing arrangement caps recommended at its March 2026.
PD-(L)1 inhibitors - Sponsor Guidance to seek broad (multi-cancer) listing of PD-(L)1 inhibitors Other business (Other matters)	Not applicable	To consider and advise on drafted departmental guidance for sponsors seeking a broad (multi-cancer) listing of PD-(L)1 inhibitors
Post Market Review (PMR) work plan Various drugs, forms, brands and sponsors Post-market review (PBS review)	Various indications	To note an update on the status of the current PMR research projects and advise on any new PMRs or preliminary research topics.

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RANIBIZUMAB Solution for ocular implant 39.5 mg in 0.395 mL Susvimo® Roche Products Pty Ltd Matters outstanding (Change to existing listing)	Neovascular (wet) age-related macular degeneration	To reconsider ranibizumab delivered via a port delivery system followed a deferred outcome at the March 2022 PBAC meeting.
RAXTOZINAMERAN I.M. injection, suspension for injection containing raxtozinameran 30 micrograms Comirnaty® Omicron XBB.1.5 PFIZER AUSTRALIA PTY LTD (Matters outstanding)	Prevention of coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2	To consider a revised pricing offer for National Immunisation Program listing of BNT162b2-platform COVID-19 vaccine.
Review of Pulmonary Arterial Hypertension (PAH) Listings Post-market review (PBS review)	Pulmonary arterial hypertension (PAH)	To consider restriction amendments for PAH medicines to allow clinicians the option of initiating/escalating treatment based on mortality risk, rather than only based on World Health Organisation (WHO) functional class.

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RESPIRATORY SYNCYTIAL VIRUS VACCINE* Solution for injection 50 µg in 0.5 mL pre-filled syringe mResvia® MODERNA AUSTRALIA PTY LTD Category 2 (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 lower respiratory tract disease caused by RSV in individuals aged over 75 years and Aboriginal and Torres Strait Islander people aged over 60 years based on the supply of the additional information from the Department.
TUCATINIB Tablet 50 mg; Tablet 150 mg TUKYSA® Pfizer Australia Pty Ltd Matter arising from the minutes (Pricing matter)	Breast cancer	To reconsider the November 2025 recommended pricing following a revised proposal from the sponsor.

Version 2
Items to be considered at a future PBAC meeting
*Respiratory Syncytial Virus Vaccine (mResvia®)