

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) INTRACYCLE MEETING AGENDA  
SEPTEMBER 2025 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 may 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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<b>Drug Name, form(s), strength(s), Sponsor, Submission type</b> Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing	<b>Drug Type and Use</b> What is the drug used to treat?	<b>Listing requested by Sponsor / Purpose of Submission</b> Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased.
<p>DAPAGLIFLOZIN</p> <p>Tablet 10 mg (as propanediol monohydrate)</p> <p>Forxiga</p> <p>ASTRAZENECA PTY LTD</p> <p>Category 3 (Change to existing listing)</p>	<p>Chronic kidney disease (CKD)</p>	<p>To consider amending the General Schedule Authority Required (STREAMLINED) listing for the treatment of CKD to align with the broader population recommended in May 2025 for empagliflozin.</p>
<p>MOGAMULIZUMAB</p> <p>Solution concentrate for I.V. infusion 20 mg in 5 mL</p> <p>Poteligeo</p> <p>Kyowa Kirin Australia Pty Ltd</p> <p>Matters arising from the minutes (New PBS listing)</p>	<p>Cutaneous T-cell lymphoma (CTCL)</p>	<p>To consider the sponsor’s proposal for listing mogamulizumab for the treatment of CTCL. This matter was considered at the March 2025 PBAC Meeting.</p>

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<p>NIVOLUMAB + IPILIMUMAB</p> <p>NIVOLUMAB                      Injection concentrate for I.V. infusion 40 mg in 4 mL                      Injection concentrate for I.V. infusion 100 mg in 10 mL                      Opdivo®</p> <p>IPILIMUMAB                      Injection concentrate for I.V. infusion 50 mg in 10 mL                      Injection concentrate for I.V. infusion 200 mg in 40 mL                      Yervoy®</p> <p>BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD</p> <p>Other matters                      (Change to existing listing)</p>	<p>Unresectable advanced and metastatic cancer</p>	<p>To consider a proposal for an expanded listing to facilitate broad access for the treatment of unresectable advanced and metastatic cancer. This matter was deferred at the July 2025 PBAC Meeting.</p>
<p>OSIMERTINIB</p> <p>Tablet 40 mg                      Tablet 80 mg</p> <p>Tagrisso®</p> <p>ASTRAZENECA PTY LTD</p> <p>Early re-entry                      (Change to existing listing)</p>	<p>Non-small cell lung cancer (NSCLC)</p>	<p>To request a General Schedule Authority Required (Telephone/Online) listing for the first line treatment of Stage IIIB (locally advanced) or Stage IV (metastatic) epidermal growth factor receptor mutation-positive (EGFRm) NSCLC in combination with pemetrexed and platinum-based chemotherapy.</p>

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<p>VANZACAFITOR WITH TEZACAFITOR AND WITH DEUTIVACAFITOR</p> <p>Pack containing 84 tablets vanzacaftor 4 mg with tezacaftor 20 mg and with deutivacaftor 50 mg                      Pack containing 56 tablet vanzacaftor 10 mg with tezacaftor 50 mg and with deutivacaftor 125 mg</p> <p>Alyftrek®</p> <p>VERTEX PHARMACEUTICALS PTY LTD</p> <p>Matters outstanding                      (New PBS listing)</p>	<p>Cystic fibrosis</p>	<p>To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of cystic fibrosis in patients who are aged 6 years and older and who have at least one F508del mutation or another responsive mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.</p>
<p>ZOLBETUXIMAB</p> <p>Powder for I.V. infusion 100 mg (20 mg per mL)</p> <p>Vyloy®</p> <p>ASTELLAS PHARMA AUSTRALIA PTY LTD</p> <p>Matters outstanding                      (New PBS listing)</p>	<p>Gastric or gastroesophageal junction (G/GOJ) cancer</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the first-line treatment of locally advanced unresectable or metastatic epidermal growth factor receptor 2-negative G/GOJ adenocarcinoma whose tumours are CLDN18.2- positive. This matter was deferred at the March 2025 PBAC Meeting.</p>

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Post Market Review (PMR) work plan  Various drugs, strengths, brands and sponsors  Post-market review (PBS review)	Various indications	To provide the PBAC with an update on the status of current post-market review research projects for noting and request PBAC advice on the Attention Deficit Hyperactivity Disorder (ADHD) medicine review.

Version 2

Items added or amended

1. VANZACAFTOR WITH TEZACAFTOR AND WITH DEUTIVACAFTOR – Added