

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) INTRACYCLE MEETING AGENDA  
DECEMBER 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 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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<p style="text-align: center;"><b>Drug Name, form(s), strength(s), Sponsor, Submission type</b> (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p style="text-align: center;"><b>Drug Type and Use</b> (What is the drug used to treat?)</p>	<p style="text-align: center;"><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>
<p style="text-align: center;">BLINATUMOMAB</p> <p style="text-align: center;">Powder for I.V. infusion 38.5 micrograms</p> <p style="text-align: center;">Blinicyto</p> <p style="text-align: center;">AMGEN AUSTRALIA PTY LTD</p> <p style="text-align: center;">(Change to existing listing - Internal submission)</p>	<p style="text-align: center;">Acute lymphoblastic leukaemia (ALL) Precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL)</p>	<p style="text-align: center;">To consider an amendment to clarify that newly-diagnosed B-ALL Ph+ patients have a subsidised chemotherapy-free option: Induction treatment with a tyrosine kinase inhibitor (TKI) and corticosteroids, and consolidation treatment that includes blinatumomab.</p>
<p style="text-align: center;">EPLERENONE</p> <p style="text-align: center;">Tablet 25 mg Tablet 50 mg</p> <p style="text-align: center;">Inspra®</p> <p style="text-align: center;">VIATRIS PTY LTD</p> <p style="text-align: center;">(Matters outstanding)</p>	<p style="text-align: center;">Heart failure</p>	<p style="text-align: center;">To request the PBAC consider an amendment to the clinical criteria for eplerenone to align with clinical guidelines for the management of heart failure. This item was deferred at the July 2025 PBAC meeting</p>

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<p style="text-align: center;">RAXTOZINAMERAN</p> <p>I.M. injection, suspension for injection containing raxtozinameran 30 micrograms</p> <p style="text-align: center;">Comirnaty® Omicron XBB.1.5</p> <p style="text-align: center;">PFIZER AUSTRALIA PTY LTD</p> <p style="text-align: center;">(Matters outstanding)</p>	<p style="text-align: center;">New vaccine - Prevention of coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2</p>	<p style="text-align: center;">To request a National Immunisation Program listing for the prevention of coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus in adults aged ≥ 18 years at increased risk of severe COVID-19 disease.</p>
<p style="text-align: center;">DESIGNATED REGISTERED NURSE PRESCRIBING</p> <p style="text-align: center;">(Internal submission - Other matters)</p>	<p style="text-align: center;">Not Applicable</p>	<p style="text-align: center;">To endorse developed principles that will be used to assess the suitability of each medicine for designated registered nurse PBS prescribing.</p>

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<p style="text-align: center;">PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p style="text-align: center;">Keytruda</p> <p style="text-align: center;">MERCK SHARP &amp; DOHME (AUSTRALIA) PTY LTD</p> <p>(Change to existing listing - Internal submission)</p>	<p style="text-align: center;">Advanced and metastatic cancers</p>	<p style="text-align: center;">To consider a revised proposal for a broad (multi-cancer) listing for pembrolizumab for advanced and metastatic cancers.</p>
<p style="text-align: center;">RESPIRATORY SYNCYTIAL VIRUS VACCINE</p> <p>Powder and suspension for injection (0.5 mL)</p> <p style="text-align: center;">Arexvy</p> <p style="text-align: center;">GLAXOSMITHKLINE AUSTRALIA PTY LTD</p> <p style="text-align: center;">(Matters Outstanding)</p>	<p style="text-align: center;">Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)</p>	<p style="text-align: center;">To request National Immunisation Program (NIP) listing for the prevention of lower respiratory tract illness (LRTI) caused by RSV for adults 75 years of age and above, and for Aboriginal and Torres Strait Islander peoples aged 60 to 74 years.</p>

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<p>SELADELPAR</p> <p>Capsule 10 mg</p> <p>Livdelzi®</p> <p>GILEAD SCIENCES PTY LTD</p> <p>(Matters outstanding)</p>	<p>Primary biliary cholangitis (PBC)</p>	<p>To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of PBC in patients who have had an inadequate response to first line therapy with ursodeoxycholic acid (UDCA) or are intolerant to UDCA.</p>
<p>VELMANASE ALFA</p> <p>Powder for I.V. infusion 10 mg,</p> <p>Lamzede®</p> <p>CHIESI AUSTRALIA PTY LTD</p> <p>( New listing Category 1)</p>	<p>Alpha-mannosidosis</p>	<p>To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing as an enzyme replacement therapy for the treatment of non-neurological manifestations in patients with alpha-mannosidosis.</p>

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