

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) INTRACYCLE MEETING AGENDA
DECEMBER 2023 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 but can also relate to new medicines.

Consumers have the opportunity to provide comments on new medicine submissions. Consumer comments already received in relation to medicines subject to a resubmission 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 align="center">Drug Name, form(s), strength(s), Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p align="center">Drug Type and Use (What is the drug used to treat?)</p>	<p align="center">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.)</p>
<p align="center">NIVOLUMAB + IPILIMUMAB</p> <p align="center">NIVOLUMAB Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL</p> <p align="center">Opdivo®</p> <p align="center">IPILIMUMAB Injection concentrate for I.V. infusion 50 mg in 10 mL Injection concentrate for I.V. infusion 200 mg in 40 mL</p> <p align="center">Yervoy®</p> <p align="center">Bristol-Myers Squibb Australia Pty Ltd</p> <p align="center">(Change to listing)</p>	<p align="center">Multiple indications</p>	<p align="center">To consider a proposal for an expanded listing to facilitate broad access to indications with current or future Therapeutic Goods Administration registration.</p>
<p align="center">PATISIRAN</p> <p align="center">Solution concentrate for I.V. infusion 10 mg in 5 mL</p> <p align="center">Onpatro®</p> <p align="center">Anylam Australia Pty Ltd</p> <p align="center">(New PBS listing)</p>	<p align="center">Hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis)</p>	<p align="center">To consider a resubmission requesting the listing of patisiran for the treatment of hATTR amyloidosis with polyneuropathy.</p>

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<p align="center">PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p align="center">Keytruda®</p> <p align="center">Merck Sharp & Dohme (Australia) Pty Ltd</p> <p align="center">(Change to listing)</p>	<p align="center">Multiple indications</p>	<p align="center">To consider a proposal for an expanded listing to facilitate broad access to indications with current or future Therapeutic Goods Administration registration.</p>
<p align="center">UPADACITINIB</p> <p align="center">Tablet 15 mg</p> <p align="center">Rinvoq®,</p> <p align="center">Abbvie Pty Ltd</p> <p align="center">(Change to listing)</p>	<p align="center">Severe active rheumatoid arthritis (RA)</p>	<p align="center">A resubmission to request a change to the restriction level of upadacitinib in the subsequent continuing treatment of RA from Authority Required (Written) to Authority Required (STREAMLINED).</p>

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ALECTINIB, BRIGATINIB, CERITINIB, CRIZOTINIB, ENTRECTINIB, AND LORLATINIB All forms and strengths Various brands Various sponsors (Change to listing)	Non-small cell lung cancer (NSCLC)	To consider a proposed change to the restriction criteria to amend testing requirements for identification of anaplastic lymphoma kinase (ALK) or c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material to include next generation sequencing small gene panel testing for NSCLC as an eligible testing method for PBS subsidy in addition to fluorescence in situ hybridisation (FISH) testing, following the 1 November 2023 listing of NGS small gene panel testing for NSCLC on the Medicare Benefits Schedule.
ASCIMINIB, DASATINIB, IMATINIB, NILOTINIB, AND PONATINIB All forms and strengths Various brands Various sponsors (Change to listing)	Chronic myeloid leukaemia (CML)	To consider updates to the restrictions of tyrosine kinase inhibitors for the treatment of CML to align with current clinical practice.

Version 2

Items amended

1. NIVOLUMAB plus IPILIMUMAB (Opdivo® and Yervoy®) – Forms amended
2. PEMBROLIZUMAB (Keytruda®) – Form amended