PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) INTRACYCLE MEETING AGENDA
DECEMBER 2021 PBAC INTRACYCLE MEETING

Only submission-related items are included on the intracycle web agenda.
Please note that items in this agenda are subject to change at short notice.

The PBAC Intracycle agenda primarily consists of applications relating to the listing of a drug or vaccine on the PBS or the National Immunisation Program.

The PBAC agenda consists of the following:
1 Minutes of Previous Meeting
2 Chairman's report (verbal)
3 Matters arising from the minutes
4 Matters arising/outstanding
7 Resubmissions
8 Pricing Matters
9 Matters relating to PBS review
10 Subcommittee and Working Party reports
11 Other business
12 Correspondence
13 Further information
14 Late papers
15 Tabled papers

Consumer comments already received for drug submissions 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.)
LORLATINIB Tablet 25 mg Tablet 100 mg Lorviqua® Pfizer Australia Pty Ltd (Change to PBS listing)	Locally advanced (stage IIIB) or metastatic (stage IV) anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC)	To request a General Schedule, Authority Required (online/telephone) listing for the treatment of locally advanced (Stage IIIB) or metastatic (Stage IV) ALK-positive NSCLC in patients who have not received prior treatment with an ALK inhibitor.
LUMACAFTOR + IVACAFTOR Tablet containing lumacaftor 100 mg with ivacaftor 125 mg Orkambi® Vertex Pharmaceuticals (Australia) Pty. Ltd.	Cystic fibrosis	To provide additional data as specified in the Managed Access Program.

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ELEXACAFTOR/TEZECAFTOR/IVACAFTOR Pack containing 56 tablets of elexacaftor 100 mg with tezacaftor 50 mg and ivacaftor 75 mg and 28 tablets of ivacaftor 150 mg Trikafta® Vertex Pharmaceuticals (Australia) Pty. Ltd. (New PBS listing)	Cystic fibrosis	Early re-entry submission to request PBS listing for CF in patients aged 12 years or older who have at least one F508del mutation on the cystic fibrosis transmembrane conductance regulator (CFTR) gene.