PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) INTRACYCLE MEETING AGENDA
DECEMBER 2022 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.

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.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) INTRACYCLE MEETING AGENDA
DECEMBER 2022 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.

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.)
ACALABRUTINIB Capsule 100 mg Calquence® AstraZeneca Pty Ltd (Change to PBS listing)	Chronic lymphocytic leukaemia or small lymphocytic lymphoma	A resubmission to request a General Schedule Authority Required listing, for use in combination with obinutuzumab, for the treatment of previously untreated chronic lymphocytic leukaemia or small lymphocytic lymphoma in patients who are unsuitable for fludarabine-based chemoimmunotherapy.
IBRUTINIB Capsule 140 mg Imbruvica® Janssen-Cilag Pty Ltd (Change to PBS listing)	Chronic lymphocytic leukaemia or small lymphocytic lymphoma	To request a General Schedule Authority Required (Written) listing, for use in combination with venetoclax, for the treatment of previously untreated chronic lymphocytic leukaemia or small lymphocytic lymphoma.
TIXAGEVIMAB AND CILGAVIMAB Pack containing 1 vial of tixagevimab 150 mg in 1.5 mL and 1 vial of cilgavimab 150 mg in 1.5 mL Evusheld® AstraZeneca Pty Ltd (New PBS listing)	Pre-exposure prevention of COVID-19	A resubmission to request a General Schedule Authority Required listing for pre-exposure prevention of COVID-19 in individuals 12 years or older who are severely immunocompromised due to a specific medical condition or because of treatment with immunosuppressive therapies that render them unlikely to mount an adequate immune response to immunisation.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) INTRACYCLE MEETING AGENDA
DECEMBER 2022 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.

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.)
TRASTUZUMAB DERUXTECAN Powder for I.V. infusion 100 mg Enhertu® AstraZeneca Pty Ltd (New PBS listing)	Breast cancer	A resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Written) listing for the treatment of human epidermal growth factor receptor 2 positive (HER2) metastatic breast cancer in patients whose disease has progressed following treatment with at least one prior HER2-directed regimen in the metastatic setting or whose disease has progressed during or within 6 months following HER2-directed adjuvant treatment.