

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) INTRACYCLE MEETING AGENDA
SEPTEMBER 2024 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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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.)
FRUQUINTINIB Capsule 1 mg Capsule 5 mg Fruzaqla® TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD. (New listing)	Metastatic colorectal cancer (mCRC)	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of patients with mCRC who have been previously treated with or who are not considered candidates for available therapies.
OSILODROSTAT Tablet 1 mg Tablet 5 mg Isturisa® RECORDATI RARE DISEASES AUSTRALIA PTY. LTD. (New listing)	Cushing syndrome	Resubmission to request a General Schedule Authority Required (Telephone/Online) listing for the treatment of endogenous Cushing syndrome.
Post-market Review (PMR) Workplan Update	N/A	To: - consider the PMR workplan, including the status of current research projects and the implementation of recently completed work. - seek advice on potential PMR topics or research projects.

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Programmed cell death protein 1/death ligand 1 (PD-(L)1) inhibitors Multiple strengths Multiple brands Multiple Sponsors (Other business)	Multiple indications	To provide initial guidance on parameters that need to be considered for future broad PBS listing proposals for PD-(L)1 inhibitors, and to advise on next steps to seek broader stakeholder input.
Review of PBS items that may be suitable for endorsed midwife (EM) prescribing Multiple strengths Multiple brands Multiple sponsors (PBS review)	Multiple indications	To consider a list of PBS items that may be suitable for prescribing by endorsed midwives.

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<p>Utilisation review of PBS listed medicines for heart failure</p> <p align="center">Multiple strengths</p> <p align="center">Multiple brands</p> <p align="center">Multiple sponsors</p> <p align="center">(PBS review)</p>	<p align="center">Medicines with the PBS indication of heart failure</p>	<p align="center">To note the utilisation review of PBS listed medicines for heart failure, consider advice on the review from the Drug Utilisation Sub Committee, and advise the Department on any further work that may be required.</p>