

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) INTRACYCLE MEETING AGENDA
SEPTEMBER 2023 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](#).

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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.)
<p align="center">CABOTEGRAVIR</p> <p align="center">Suspension for injection 600 mg in 3 mL</p> <p align="center">Apretude®</p> <p align="center">ViiV HEALTHCARE PTY LTD</p> <p align="center">(New PBS listing)</p>	<p align="center">Pre-exposure prophylaxis for human immunodeficiency virus (HIV) infection</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing for use as pre-exposure prophylaxis for HIV infection in persons in whom tenofovir/emtricitabine is contraindicated.</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">ALNYLAM AUSTRALIA PTY LTD</p> <p align="center">(New PBS listing)</p>	<p align="center">Hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis)</p>	<p align="center">A resubmission requesting the listing of patisiran for the treatment of hATTR amyloidosis in adult patients with stage 1 or stage 2 polyneuropathy.</p>
<p align="center">TEBENTAFUSP</p> <p align="center">Solution concentrate for I.V. infusion 100 mcg in 0.5 mL vial</p> <p align="center">Kimmtrak®</p> <p align="center">Synevi Pty Limited</p> <p align="center">(New PBS listing)</p>	<p align="center">Advanced (unresectable or metastatic) human leukocyte antigen (HLA)-A*02:01-positive uveal melanoma</p>	<p align="center">A resubmission requesting the listing of tebentafusp for the treatment of HLA-A*02:01-positive adult patients with advanced (unresectable or metastatic) uveal melanoma.</p>

Version 2
Item added

1. CABOTEGRAVIR (Apretude®) –added