

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

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<p align="center"><b>Drug Name, form(s), strength(s), Sponsor, Submission type</b> (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p align="center"><b>Drug Type and Use</b> (What is the drug used to treat?)</p>	<p align="center"><b>Listing requested by Sponsor / Purpose of Submission</b> (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">AZACITIDINE</p> <p align="center">Tablet 200 mg Tablet 300 mg</p> <p align="center">Onureg®</p> <p align="center">Celgene Pty Limited</p> <p align="center">(New PBS listing)</p>	<p align="center">Acute myeloid leukaemia</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing for maintenance therapy in certain patients with acute myeloid leukaemia who are not candidates for, including those who choose not to proceed to, haematopoietic stem cell transplantation.</p>
<p align="center">QUADRIVALENT INFLUENZA VACCINE (SURFACE ANTIGEN, INACTIVATED, CELL-BASED)</p> <p align="center">Injection 15 microgram in 0.5 mL needle-free pre-filled syringe Injection 15 microgram in 0.5 mL pre-filled syringe with attached needle</p> <p align="center">Flucelvax® Quad</p> <p align="center">Seqirus (Australia) Pty Ltd</p> <p align="center">(New listing)</p>	<p align="center">Prevention of influenza</p>	<p align="center">To request National Immunisation Program listing for the prevention of influenza.</p>

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<p align="center">RUXOLITINIB</p> <p align="center">Tablet 5 mg Tablet 10 mg</p> <p align="center">Jakavi®</p> <p align="center">Novartis Pharmaceuticals Australia Pty Limited</p> <p align="center">(Change to PBS listing)</p>	<p align="center">Graft versus host disease</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of patients with moderate to severe chronic graft versus host disease (GVHD) who are refractory to, dependent on or intolerant of corticosteroids.</p>
<p align="center">TIXAGEVIMAB AND CILGAVIMAB</p> <p>Pack containing 1 vial of tixagevimab 150 mg in 1.5 mL and 1 vial of cilgavimab 150 mg in 1.5 mL</p> <p align="center">Evusheld®</p> <p align="center">Astrazeneca Pty Ltd</p> <p align="center">(New listing)</p>	<p align="center">Pre-exposure prevention of COVID-19</p>	<p>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.</p>

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<p align="center">VOSORITIDE</p> <p>Powder for injection 0.4 mg with diluent                      Powder for injection 0.56 mg with diluent                      Powder for injection 1.2 mg with diluent</p> <p align="center">Voxzogo®</p> <p align="center">BioMarin Pharmaceutical Australia Pty Ltd</p> <p align="center">(New listing)</p>	<p align="center">Achondroplasia</p>	<p align="center">To request a General Schedule Authority Required listing for the treatment of patients with achondroplasia whose epiphyses are not closed.</p>

Version 2

Items amended

1. RUXOLITINIB (Jakavi®) – Purpose of submission for item amended