

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) INTRACYCLE MEETING AGENDA
MAY 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">Drug Name, form(s), strength(s), Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p align="center">Drug Type and Use (What is the drug used to treat?)</p>	<p align="center">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>
<p align="center">BUROSUMAB</p> <p align="center">Injection 10 mg in 1 mL Injection 20 mg in 1 mL Injection 30 mg in 1 mL</p> <p align="center">Crysvita®</p> <p align="center">Kyowa Kirin Australia Pty Ltd</p> <p align="center">(New PBS listing)</p>	<p align="center">X-linked hypophosphataemia</p>	<p align="center">Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of X-linked hypophosphataemia.</p>
<p align="center">DARATUMUMAB</p> <p align="center">Solution for subcutaneous injection 1,800 mg in 15 mL vial</p> <p align="center">Darzalex SC®</p> <p align="center">Janssen-Cilag Pty Ltd</p> <p align="center">(New PBS listing)</p>	<p align="center">Amyloid light-chain (AL) amyloidosis</p>	<p align="center">Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (Telephone) listing, for use in combination with cyclophosphamide, bortezomib and dexamethasone, for the treatment of patients with newly diagnosed AL amyloidosis.</p>

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<p align="center">DULAGLUTIDE</p> <p>Injection 3 mg in 0.5 mL single dose pre-filled pen Injection 4.5 mg in 0.5 mL single dose pre-filled pen</p> <p align="center">Trulicity®</p> <p align="center">Eli Lilly Australia Pty Ltd</p> <p align="center">(Matters Outstanding)</p>	<p align="center">Type 2 diabetes mellitus</p>	<p align="center">To request General Schedule Authority Required (STREAMLINED) listings of two new forms for the treatment of patients with Type 2 diabetes mellitus who require treatment intensification to achieve glycaemic targets, as dual therapy in combination with metformin.</p>
<p align="center">FARICIMAB</p> <p>Solution for intravitreal injection 28.8 mg in 0.24 mL</p> <p align="center">Vabysmo®</p> <p align="center">Roche Products Pty Ltd</p> <p align="center">(New PBS listing)</p>	<p align="center">Diabetic macular oedema (DMO)</p>	<p align="center">To request a General Schedule Authority Required (Written) listing for the treatment of DMO.</p>

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<p align="center">FARICIMAB</p> <p>Solution for intravitreal injection 28.8 mg in 0.24 mL</p> <p align="center">Vabysmo®</p> <p align="center">Roche Products Pty Ltd</p> <p align="center">(New PBS listing)</p>	<p align="center">Neovascular (wet) age-related macular degeneration (nAMD)</p>	<p align="center">To request a General Schedule Authority Required (Written) listing for the treatment of nAMD.</p>
<p align="center">PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p align="center">Keytruda®</p> <p align="center">Merck Sharp & Dohme (Australia) Pty Ltd</p> <p align="center">(Matters Outstanding)</p>	<p align="center">Gastro-oesophageal cancers</p>	<p align="center">To consider additional information provided by the sponsor in relation to the deferral of the decision to recommend the PBS listing of pembrolizumab for the treatment of gastro-oesophageal cancers.</p>

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PREGABALIN Tablet 82.5 mg Tablet 165 mg Tablet 330 mg Lyrica® CR Upjohn Australia Pty Ltd (Matters Outstanding)	Neuropathic pain	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of neuropathic pain in adults, where this condition is refractory to treatment with other drugs. The PBAC deferred making a recommendation at its November 2021 meeting and requested further information on the use of pregabalin.
PREGABALIN Oral solution 20 mg per mL, 473 mL Pregabalin-AFT AFT Pharmaceuticals (Au) Pty Ltd (Matters Outstanding)	Neuropathic pain	To request an Authority Required (streamlined) listing of pregabalin solution under the same circumstances as the existing listed pregabalin. The PBAC deferred making a recommendation at its November 2021 meeting and requested further information on the use of pregabalin.
PREGABALIN Various forms Various sponsors (Sub-committee report DUSC analysis)	Neuropathic pain	To assess the utilisation of PBS listed immediate release formulations of pregabalin.

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<p align="center">NICOTINE REPLACEMENT THERAPY</p> <p align="center">Various forms</p> <p align="center">Various sponsors</p> <p align="center">BUPROPRION</p> <p align="center">VARENCICLINE</p> <p align="center">All listed brands</p> <p align="center">Various sponsors</p> <p align="center">(Post-market Review)</p>	<p align="center">Smoking cessation therapy for nicotine dependence</p>	<p align="center">To consider the findings of the Post-market Review of medicines for smoking cessation.</p> <p align="center">To consider the findings from the CER of combinations of smoking cessation medicines recommended by the Economics Sub-Committee (ESC) of the PBAC following consideration of the Post market Review in June 2021 https://www.pbs.gov.au/info/reviews/post-market-review-of-medicines-for-smoking-cessation.</p>

Version 2:

- Added – Two (2) Early Resolutions resubmissions received (page 2).
- Added – Four (4) Matters Outstanding
- Added – One (1) Sub-committee report DUSC analysis