

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) INTRACYCLE MEETING AGENDA  
MAY 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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<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">CARMELLOSE WITH GLYCEROL AND HYALURONIC ACID</p> <p align="center">Eye drops containing carmellose sodium 5 mg with glycerol 9 mg and sodium hyaluronate 1 mg per mL, 10 mL</p> <p align="center">Optive Fusion®</p> <p align="center">Allergan Australia Pty Limited</p> <p align="center">(New PBS listing)</p>	<p align="center">Severe dry eye syndrome</p>	<p align="center">To request a General Schedule Restricted Benefit listing for the treatment of severe dry eye syndrome.</p>
<p align="center">DAROLUTAMIDE</p> <p align="center">Tablet 300 mg</p> <p align="center">Nubeqa®</p> <p align="center">Bayer Australia Ltd</p> <p align="center">(Change to PBS listing)</p>	<p align="center">Prostate cancer</p>	<p align="center">To request a General Schedule Authority Required listing, for use in combination with androgen deprivation therapy and docetaxel, for the treatment of metastatic hormone sensitive prostate cancer.</p>

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<p align="center">FLUTICASONE PROPIONATE</p> <p>Pressurised inhalation containing fluticasone propionate 50 micrograms per dose, 120 doses (CFC-free formulation)</p> <p align="center">Axotide Junior® Flixotide Junior®</p> <p align="center">GlaxoSmithKline Australia Pty Ltd</p> <p align="center">(Change to PBS listing)</p>	<p align="center">Asthma</p>	<p align="center">To review the circumstances of the General Schedule Authority Required listing for patients under 6 years with asthma.</p>
<p align="center">HYALURONIC ACID WITH POLYETHYLENE GLYCOL 400 WITH PROPYLENE GLYCOL WITH HYDROXYPROPYL GUAR</p> <p>Eye drops containing sodium hyaluronate 1.5 mg per mL with polyethylene glycol 400, propylene glycol and hydroxypropyl guar, 10 mL</p> <p align="center">Systane® Hydration</p> <p align="center">Alcon Laboratories (Australia) Pty Ltd</p> <p align="center">(New PBS listing)</p>	<p align="center">Severe dry eye syndrome</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.</p>

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<p align="center">INCLISIRAN</p> <p align="center">Injection 284 mg in 1.5 mL single use pre-filled syringe</p> <p align="center">Leqvio®</p> <p align="center">Novartis Pharmaceuticals Australia Pty Limited</p> <p align="center">(New PBS listing)</p>	<p align="center">Hypercholesterolaemia</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of hypercholesterolaemia and atherosclerotic cardiovascular disease.</p>
<p align="center">PEMBROLIZUMAB</p> <p align="center">Powder for I.V. infusion 100 mg (as disodium)</p> <p align="center">Keytruda®</p> <p align="center">Merck Sharp &amp; Dohme (Australia) Pty Ltd</p> <p align="center">(Change to PBS listing)</p>	<p align="center">Melanoma</p>	<p align="center">To consider a request from the Melanoma Institute Australia (MIA) to expand the current PBS listings for pembrolizumab for the adjuvant treatment of resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma to allow neoadjuvant treatment.</p>

Version 2

Items amended

1. CARMELLOSE WITH GLYCEROL AND HYALURONIC ACID (Optive Fusion®) – drug name and form for item amended
2. INCLISIRAN (Leqvio®) – drug name and form for item amended