

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA  
May 2025 PBAC MEETING**

**Closing date for consumer comments 26 March 2025**

The PBAC agenda primarily consists of applications relating to the new listing of a drug or vaccine on the Pharmaceutical Benefits Scheme (PBS) or the National Immunisation Program (NIP).

The PBAC agenda consists of the following:

- 1 Minutes of Previous Meeting**
- 2 Chair's report (verbal)**
- 3 Matters arising from the minutes**
- 4 Matters arising/outstanding**
- 5 New listing applications**
- 6 Requests for changes to listings**
- 7 Resubmissions**
- 8 Pricing Matters**
- 9 Matters relating to PBS review**
- 10 Subcommittee and Working Party reports**
- 11 Other business**
- 12 Correspondence**
- 13 Further information**
- 14 Late papers**
- 15 Tabled papers**
- 16 Delistings**
- 17 Positive recommendations not accepted by applicants after 2 years**

Consumers will have the opportunity to provide comments on new drug submissions (item 5), changes to listings (item 6) and resubmissions (item 7). In many circumstances, consumers will be able to comment on items in other sections of the agenda. The submissions for which input is sought will be listed in alphabetical order by drug name. There is no provision for consumer comments to the PBAC on agenda item 8 which relates to pricing matters.

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)).

Initial submissions are categorised broadly as:

- *Category 1 or 2*: Submissions to list new medicines on the Schedule of Pharmaceutical Benefits or to make substantial changes to current listings are generally classified as Category 1 or 2 submissions. These submissions require presentation of an economic evaluation.

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- *Category 3 or 4:* Submissions that relate to new forms of previously listed products and changes to the conditions of use e.g. change in maximum quantity/repeats or clarifying the wording of a restriction (while not altering the intended use) are considered to be Category 3 or 4 submissions. These submissions do not usually require the presentation of an economic evaluation.

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](#).

<b>Drug Name, form(s), strength(s) and Sponsor, Submission type</b> (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)	<b>Drug Type and Use</b> (What is the drug used to treat?)	<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.)
ALECTINIB  Capsule 150 mg  Alecensa®  ROCHE PRODUCTS PTY LTD  (Change to existing listing)	Non-small cell lung cancer (NSCLC)	To request a General Schedule Authority Required (Telephone/Online) listing for the adjuvant treatment in adult patients following tumour resection of anaplastic lymphoma kinase (ALK)-positive NSCLC (tumours ≥4 cm or node positive).

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<p align="center">BIMEKIZUMAB</p> <p>Injection 160 mg in 1 mL single use pre-filled pen Injection 160 mg in 1 mL single use pre-filled syringe Injection 320 mg in 2 mL single use pre-filled pen Injection 320 mg in 2 mL single use pre-filled syringe</p> <p align="center">Bimzelx®</p> <p align="center">UCB AUSTRALIA PROPRIETARY LIMITED</p> <p align="center">(New PBS listing)</p>	<p align="center">Hidradenitis suppurativa (HS)</p>	<p align="center">To request General Schedule Authority Required (Written) listings for new forms of bimekizumab, in addition to the currently listed form, for the treatment of patients with moderate to severe HS.</p>
<p align="center">DOSTARLIMAB</p> <p>Solution concentrate for I.V. infusion 500 mg in 10 mL</p> <p align="center">Jemperli®</p> <p align="center">GLAXOSMITHKLINE AUSTRALIA PTY LTD</p> <p align="center">(Change to existing listing)</p>	<p align="center">Endometrial cancer</p>	<p align="center">Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for use in combination with platinum-containing chemotherapy for the treatment of primary advanced or first recurrent mismatch repair proficient endometrial cancer.</p>

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<p align="center">DURVALUMAB</p> <p>Solution concentrate for I.V. infusion 120 mg in 2.4 mL Solution concentrate for I.V. infusion 500 mg in 10 mL</p> <p align="center">Imfinzi®</p> <p align="center">TREMELIMUMAB</p> <p>Solution concentrate for I.V. infusion 300 mg in 15 mL</p> <p align="center">Imjudo®</p> <p align="center">ASTRAZENECA PTY LTD</p> <p align="center">(New PBS listing)</p>	<p align="center">Barcelona clinic liver cancer (BCLC) Hepatocellular carcinoma (HCC)</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for durvalumab in combination with tremelimumab for the first line treatment of patients with advanced (unresectable) Stage B BCLC or Stage C HCC.</p>
<p align="center">EMPAGLIFLOZIN</p> <p align="center">Tablet 10 mg</p> <p align="center">Jardiance®</p> <p align="center">BOEHRINGER INGELHEIM PTY LTD</p> <p align="center">(Change to existing listing)</p>	<p align="center">Chronic kidney disease (CKD)</p>	<p align="center">Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the CKD incremental population.</p>

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ETONOGESTREL WITH ETHINYLESTRADIOL  Vaginal ring containing etonogestrel 11.7 mg with ethinylestradiol 2.7 mg  NuvaRing®  ORGANON PHARMA PTY LTD  (New PBS listing)	Contraception	To request a General Schedule Restricted Benefit listing for contraception.
FEDRATINIB  Capsule 100 mg  Inrebic®  BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD  (New PBS listing)	Myelofibrosis (MF)	To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of patients with intermediate-2/high-risk MF.
GUSELKUMAB  Injection 100 mg in 1 mL single use pre-filled pen  Tremfya®  JANSSEN-CILAG PTY LTD  (Change to existing listing)	Chronic plaque psoriasis (CPP)	To request a General Schedule Authority Required (Written) listing for the treatment of severe CPP.

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<p>INCOBOTULINUMTOXINA</p> <p>Lyophilised powder for injection 100 units</p> <p>Xeomin®</p> <p>MERZ AUSTRALIA PTY LTD</p> <p>Matters outstanding (Change to existing listing)</p>	<p>Chronic sialorrhea</p>	<p>To request a Section 100 (Botulinum Toxin Program) Authority Required (STREAMLINED) listing for the treatment of chronic sialorrhea due to neurological disorders.</p>
<p>NIRSEVIMAB</p> <p>Solution for injection 50 mg in 0.5 mL pre-filled syringe</p> <p>Solution for injection 100 mg in 1 mL pre-filled syringe</p> <p>Beyfortus®</p> <p>SANOFI-AVENTIS AUSTRALIA PTY LTD</p> <p>(New NIP listing)</p>	<p>Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)</p>	<p>Resubmission to request a National Immunisation Program listing for the prevention of RSV lower respiratory tract disease in neonates and infants born during or entering their first RSV season; and children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.</p>

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<p align="center">NIVOLUMAB + IPILIMUMAB</p> <p align="center">NIVOLUMAB Injection concentrate for I.V. infusion 40 mg in 4 mL, Injection concentrate for I.V. Infusion 100 mg in 10 mL.</p> <p align="center">Opdivo®</p> <p align="center">IPILIMUMAB Injection concentrate for I.V. infusion 50 mg in 10 mL</p> <p align="center">Yervoy®</p> <p align="center">BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD.</p> <p align="center">(Change to existing listing)</p>	<p align="center">Stage III melanoma</p>	<p align="center">To request an amendment to the current PBS listings for nivolumab and ipilimumab to allow use in the neoadjuvant setting of stage III melanoma according to the protocol used in the NADINA (Neoadjuvant Ipilimumab plus Nivolumab versus Standard Adjuvant Nivolumab in Macroscopic Stage III Melanoma) trial.</p>

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<p align="center">OMALIZUMAB</p> <p>Injection 75 mg in 0.5 mL single dose pre-filled syringe Injection 150 mg in 1 mL single dose pre-filled syringe Injection 300 mg in 2 mL single dose pre-filled syringe Injection 75 mg in 0.5 mL single dose pre-filled pen Injection 150 mg in 1 mL single dose pre-filled pen Injection 300 mg in 2 mL single dose pre-filled pen</p> <p align="center">Xolair®</p> <p align="center">NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED</p> <p align="center">(Change to existing listing)</p>	<p align="center">Chronic rhinosinusitis with nasal polyps (CRSwNP)</p>	<p align="center">To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the initial treatment and an Authority Required (Telephone/Online) listing for the continuing treatment of patients with CRSwNP.</p>
<p align="center">OSIMERTINIB</p> <p align="center">Tablet 40 mg Tablet 80 mg</p> <p align="center">Tagrisso®</p> <p align="center">ASTRAZENECA PTY LTD</p> <p align="center">(Change to existing listing)</p>	<p align="center">Non-small cell lung cancer (NSCLC)</p>	<p align="center">To request a General Schedule Authority Required (Telephone/Online) listing for the first line treatment of Stage IIIB (locally advanced) or Stage IV (metastatic) epidermal growth factor receptor mutation-positive (EGFRm) NSCLC in combination with pemetrexed and platinum-based chemotherapy.</p>

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<p align="center">PEGCETACOPLAN</p> <p>Solution for subcutaneous infusion 1,080 mg in 20 mL</p> <p align="center">Empaveli®</p> <p align="center">SWEDISH ORPHAN BIOVITRUM PTY LTD</p> <p align="center">(Change to existing listing)</p>	<p align="center">Paroxysmal nocturnal haemoglobinuria (PNH)</p>	<p align="center">To request an amendment to the existing Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of PNH to allow initial treatment with pegcetacoplan in patients who are either treatment-naïve to complement 5 (C5) inhibitors or currently treated with a C5 inhibitor.</p>
<p align="center">PIOGLITAZONE</p> <p>Tablet 15 mg (as hydrochloride) Tablet 30 mg (as hydrochloride) Tablet 45 mg (as hydrochloride)</p> <p align="center">Actos®</p> <p align="center">CELLTRION HEALTHCARE AUSTRALIA PTY LTD</p> <p align="center">(New PBS listing)</p>	<p align="center">Type 2 diabetes mellitus (T2DM)</p>	<p align="center">To request General Schedule Restricted Benefit listings for a new pack size of pioglitazone (Actos®), with an increased maximum quantity across all currently PBS-listed strengths of pioglitazone for the treatment of T2DM.</p>

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<p align="center">RANIBIZUMAB</p> <p>Solution for intravitreal injection 1.65 mg in 0.165 mL pre-filled syringe Solution for intravitreal injection 2.3 mg in 0.23 mL</p> <p align="center">Lucentis®</p> <p align="center">NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED</p> <p align="center">(Change to existing listing)</p>	<p align="center">Proliferative diabetic retinopathy (PDR)</p>	<p align="center">To request a General Schedule Authority Required (Written) listing for the initial treatment and an Authority Required (STREAMLINED) listing for the continuing treatment of patients with PDR without diabetic macular oedema.</p>
<p align="center">RAXTOZINAMERAN</p> <p>I.M. injection, suspension for injection containing raxtozinameran 30 micrograms</p> <p align="center">Comirnaty®</p> <p align="center">PFIZER AUSTRALIA PTY LTD</p> <p align="center">(New NIP listing)</p>	<p align="center">Prevention of coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2</p>	<p align="center">To request a National Immunisation Program listing for the prevention of coronavirus disease 2019 (COVID-19) in adults with medical risk conditions, immunocompromised patients aged 18 and older, or adults aged 60 years and over.</p>

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<p>REPOTRECTINIB</p> <p>Capsule 40 mg Capsule 160 mg</p> <p>Augtyro™</p> <p>BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD</p> <p>(New PBS listing)</p>	<p>Non-small cell lung cancer (NSCLC)</p>	<p>To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of locally advanced (Stage IIIB) or metastatic (Stage IV) ROS proto-oncogene 1 (ROS1)-positive NSCLC.</p>
<p>TEPROTUMUMAB</p> <p>Powder for I.V. infusion 500 mg</p> <p>Tepezza®</p> <p>AMGEN AUSTRALIA PTY LTD</p> <p>Early resolution (New PBS listing)</p>	<p>Thyroid Eye Disease (TED)</p>	<p>To consider a resubmission for a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing of teprotumumab for the treatment of active, moderate-to-severe Thyroid Eye Disease (TED).</p>
<p>TRASTUZUMAB DERUXTECAN</p> <p>Powder for I.V. infusion 100 mg</p> <p>Enhertu®</p> <p>ASTRAZENECA PTY LTD</p> <p>(Change to existing listing)</p>	<p>Gastric or gastroesophageal junction (G/GOJ) cancer</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for the treatment of metastatic human epidermal growth factor receptor 2-positive (HER2+) G/GOJ cancer following trastuzumab therapy.</p>

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UBLITUXIMAB  Solution concentrate for I.V. infusion 150 mg in 6 mL (25 mg per mL)  Briumvi®  KIRCHMANN ENTERPRISES PTY LTD  (New PBS listing)	Relapsing-remitting multiple sclerosis (RRMS)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of RRMS.

*Non-submission items*

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ATAGI Recommendations regarding the Paediatric Pneumococcal Schedule  Multiple forms, strengths, brands and sponsors  (Other matters)	Pneumococcal disease	To consider and endorse ATAGI recommendations for an updated Paediatric Pneumococcal Schedule.

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<p>FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL</p> <p>100mcg/62.5mcg/25mcg 200mcg/62.5mcg/25mcg</p> <p>Trelegy Ellipta®</p> <p>GLAXOSMITHKLINE AUSTRALIA PTY LTD</p> <p>(Sub-committee report DUSC analysis)</p>	<p>Severe Asthma</p>	<p>To assess the utilisation of PBS listed fluticasone furoate + umeclidinium + vilanterol (Trelegy Ellipta®) and single inhaler triple therapies for the treatment of severe asthma.</p>
<p>MEDICINES FOR GASTROINTESTINAL STROMAL TUMOUR</p> <p>All brands and strengths</p> <p>Various sponsors</p> <p>(Sub-committee report DUSC Analysis)</p>	<p>Gastrointestinal Stromal Tumour</p>	<p>To assess the utilisation of PBS listed medicines for the treatment of gastrointestinal stromal tumour.</p>
<p>ZANUBRUTINIB</p> <p>Capsule 80 mg</p> <p>Brukinsa®</p> <p>BEIGENE AUS PTY LTD</p> <p>(Sub-committee report DUSC analysis)</p>	<p>Waldenström Macroglobulinaemia</p>	<p>To assess the utilisation of PBS listed zanubrutinib for the treatment of Waldenström Macroglobulinaemia.</p>

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<p>Review of antiepileptic drugs (AEDs)</p> <p>Multiple Forms</p> <p>Multiple Brands</p> <p>Multiple Sponsors</p> <p>(PBS review)</p>	<p>Epilepsy</p>	<p>To consider amending the current PBS listings for the second-line AEDs, levetiracetam (LEV) and lamotrigine (LTG), to allow their first-line use in the general Australian population with epilepsy.</p>
<p>Review of PBS Prescriber Bag</p> <p>(PBS review)</p>	<p>Various medicines and sponsors</p>	<p>To seek the PBAC's advice on the purpose and intent of the Prescriber Bag Schedule, taking into account written submissions from stakeholders, and to ensure that Prescriber Bag listings reflect contemporary clinical need. This will inform the Department's work on a review of the PBS Prescriber Bag, which will be considered by the PBAC at a future meeting.</p>

Version 5

Items added or amended

INCOBOTULINUMTOXINA (Xeomin<sup>®</sup>) – Added to reflect the last-minute addition of an item deferred from the November 2024 PBAC meeting

Items added or amended previously

1. ATAGI Recommendations regarding the Paediatric Pneumococcal Schedule - Added
2. Review of antiepileptic drugs (AEDs) – Added
3. Review of PBS Prescriber Bag – Added
4. NIVOLUMAB with IPILIMUMAB (Opdivo<sup>®</sup> and Yervoy<sup>®</sup>) – Added
5. PIOGLITAZONE (Actos<sup>®</sup>) – Added
6. TEPROTUMUMAB (Tepezza<sup>®</sup>) – Added
7. FLUTICASON FUROATE + UMECLIDINIUM + VILANTEROL (Trelegy Ellipta<sup>®</sup>) – Added
8. MEDICINES FOR GASTROINTESTINAL STROMAL TUMOUR (All brands) – Added
9. NIRSEVIMAB (Beyfortus<sup>®</sup>) – Added
10. ZANUBRUTINIB (Brukinsa<sup>®</sup>) – Added