

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2025 PBAC MEETING

Closing date for consumer comments 24 September 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](#).

The PBAC meeting agenda will be published in week 3 – and updated in week 8 (to include early pathway resubmissions, and items for review under the process for reviewing positive PBS-listing recommendations not accepted by applicants) in each PBAC cycle as per [PBS Calendar](#).

Drug Name, form(s), strength(s) and Sponsor, Submission type, PBS schedule (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, requested authority level (Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased.)
21-VALENT PNEUMOCOCCAL CONJUGATE VACCINE Injection, 0.5 mL Capvaxive® MERCK SHARP & DOHME (AUSTRALIA) PTY LTD (New NIP listing)	Prevention of pneumococcal disease in adults	To request a National Immunisation Program (NIP) listing for the prevention of pneumococcal disease for: <ul style="list-style-type: none"> • adults who are currently eligible to receive the 13-valent pneumococcal conjugate vaccine under the NIP (adults under 70 with specified medical risk conditions, Aboriginal and Torres Strait Islander adults over 50 years of age, and all adults over 70 years of age) and • Aboriginal and Torres Strait Islander people aged 25 to 49.

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<p>ACALABRUTINIB Tablet 100 mg Calquence® ASTRAZENECA PTY LTD (Change to existing listing) PBS General Schedule</p>	<p>Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)</p>	<p>To request listing of acalabrutinb for use in combination with venetoclax for the treatment of previously untreated CLL or SLL. Authority Required (Telephone/Online)</p>
<p>AFLIBERCEPT Solution for intravitreal injection 3.6 mg in 90 microlitres (40 mg per mL) pre-filled syringe Solution for intravitreal injection 4 mg in 100 microlitres (40 mg per mL) Eydenzelt® CELLTRION HEALTHCARE AUSTRALIA PTY LTD (New PBS listing) PBS General Schedule</p>	<p>Subfoveal choroidal neovascularisation (CNV) due to pathologic myopia (PM)</p>	<p>To request listing of a new aflibercept biosimilar for the treatment of CNV due to PM that mirrors the originator brand's current listing. Authority Required</p>

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<p>BELANTAMAB MAFODOTIN</p> <p>Powder for injection 70 mg (50 mg per ml) Powder for injection 100 mg (50 mg per ml)</p> <p>Blenrep®</p> <p>GLAXOSMITHKLINE AUSTRALIA PTY LTD</p> <p>(New PBS listing)</p> <p>PBS Section 100 (Efficient Funding of Chemotherapy Program)</p>	<p>Relapsed and/or refractory multiple myeloma (MM)</p>	<p>To request listings of belantamab mafodotin for use in combination with bortezomib and dexamethasone for initial and continuing treatment of relapsed and/or refractory MM after one prior line of therapy.</p> <p>Authority Required (Telephone/Online) listing for initial treatment Authority Required (STREAMLINED) listing for continuing treatment</p>
<p>BIMEKIZUMAB</p> <p>Injection 320 mg in 2 mL single use pre-filled pen</p> <p>Bimzelx®</p> <p>UCB AUSTRALIA PROPRIETARY LIMITED</p> <p>(New PBS listing)</p> <p>PBS General Schedule</p>	<p>Severe chronic plaque psoriasis (CPP)</p>	<p>To request a listing of a new strength of bimekizumab for the treatment of severe CPP.</p> <p>Authority Required</p>

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<p>CALCIPOTRIOL WITH BETAMETHASONE</p> <p>Gel containing calcipotriol 50 micrograms with betamethasone 500 micrograms (as dipropionate) per g, 60 g</p> <p>Actobet®</p> <p>ACTOR PHARMACEUTICALS PTY LTD</p> <p>(New PBS listing)</p> <p>PBS General Schedule</p>	<p>Chronic stable plaque type psoriasis vulgaris</p>	<p>To request listing of a new form of calcipotriol with betamethasone for the treatment of chronic stable plaque type psoriasis vulgaris.</p> <p>Restricted Benefit</p>
<p>CETRORELIX</p> <p>Solution for injection 250 micrograms (as acetate) in 1 mL single use pre-filled syringe</p> <p>Femvi®</p> <p>SUN PHARMA ANZ PTY LTD</p> <p>(New PBS listing)</p> <p>PBS Section 100 (In Vitro Fertilisation Program)</p>	<p>Assisted Reproductive Technology (ART)</p>	<p>To request a listing of a new form of cetorelix for use in ART.</p> <p>Authority Required (STREAMLINED)</p>

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DELGOCITINIB Cream 20 mg per g, 60 g Anzupgo® LEO PHARMA PTY LTD (New PBS listing) PBS General Schedule	Chronic hand eczema (CHE)	To request listing of delgocitinib for the treatment of moderate to severe CHE where topical corticosteroids failed to achieve an adequate response or are medically inappropriate. Authority Required (Written)
DENOSUMAB Injection 60 mg in 1 mL pre-filled syringe Stoboclo® Injection 120 mg in 1.7 mL Osenvelt® CELLTRION HEALTHCARE AUSTRALIA PTY LTD (New PBS listing) PBS General Schedule	Osteoporosis Giant cell tumour of bone Bone metastases	To request listings of two new denosumab biosimilars that mirror their respective originator brand's current listings. Authority Required (STREAMLINED)

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<p>DESMOPRESSIN</p> <p>Nasal spray (pump pack) containing desmopressin acetate 10 micrograms per actuation, 50 actuations, 5 mL</p> <p>Desmomed</p> <p>MEDSURGE HEALTHCARE PTY LTD</p> <p>(New PBS listing)</p> <p>PBS General Schedule</p>	<p>Cranial diabetes insipidus Primary nocturnal enuresis</p>	<p>To request listing of a new desmopressin acetate 10 microgram per actuation nasal spray with a different pack size that mirrors the originator brand's current PBS listings.</p> <p>Authority Required (STREAMLINED)</p>
<p>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>Imfinzi®</p> <p>ASTRAZENECA PTY LTD</p> <p>(Change to existing listing)</p> <p>PBS Section 100 (Efficient Funding of Chemotherapy Program)</p>	<p>Muscle invasive bladder cancer (MIBC)</p>	<p>To request listing of durvalumab for the perioperative treatment (i.e. before and after surgery) of patients with MIBC who are planning to undergo radical cystectomy and are eligible for cisplatin-based neoadjuvant chemotherapy (i.e. eligible for cisplatin-based chemotherapy given prior to surgery).</p> <p>Authority Required (STREAMLINED)</p>

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<p>EFGARTIGIMOD ALFA</p> <p>Solution for subcutaneous injection 1000 mg in 5.6 mL</p> <p>Vyvgart®</p> <p>ARGENX AUSTRALIA PTY. LTD.</p> <p>(New PBS listing)</p> <p>PBS General Schedule</p>	<p>Generalised myasthenia gravis (gMG)</p>	<p>To request a subcutaneous injection form of efgartigimod alfa for initial and continuing treatment of adult patients with gMG who are anti-acetylcholine receptor antibody positive.</p> <p>Authority Required</p>
<p>ENCORAFENIB</p> <p>Capsule 75 mg</p> <p>Braftovi®</p> <p>BINIMETINIB</p> <p>Tablet 15 mg Tablet 45 mg</p> <p>Mektovi®</p> <p>PIERRE FABRE AUSTRALIA PTY LTD</p> <p>(New PBS listing)</p> <p>PBS General Schedule</p>	<p>Non-small cell lung cancer (NSCLC)</p>	<p>To request listing of encorafenib for use in combination with binimetinib for the treatment of adult patients with advanced or metastatic NSCLC with a BRAF V600E mutation who have not received prior systemic treatment in the metastatic setting.</p> <p>Authority Required (STREAMLINED)</p>

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<p>ESTRADIOL WITH PROGESTERONE</p> <p>Capsule containing estradiol 1mg (as hemihydrate) with progesterone 100mg</p> <p>Bijuva®</p> <p>THERAMEX AUSTRALIA PTY LTD</p> <p>(New PBS listing)</p> <p>PBS General Schedule</p>	<p>Vasomotor symptoms in post-menopausal women</p>	<p>To request listing of estradiol with progesterone for the treatment of moderate to severe vasomotor symptoms in post-menopausal women.</p> <p>Restricted Benefit</p>
<p>FEDRATINIB</p> <p>Capsule 100 mg</p> <p>Inrebic®</p> <p>BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD</p> <p>(New PBS listing)</p> <p>PBS General Schedule</p>	<p>Myelofibrosis (MF)</p>	<p>Resubmission to request listing of fedratinib for the treatment of patients with intermediate/high-risk primary myelofibrosis, post-polycythaemia vera myelofibrosis, or post-essential thrombocythaemia myelofibrosis.</p> <p>Authority Required (Telephone/Online)</p>

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<p>FENFLURAMINE</p> <p>Oral solution 2.2 mg (as hydrochloride) per mL, 360 mL</p> <p>Fintepla®</p> <p>UCB AUSTRALIA PROPRIETARY LIMITED</p> <p>(Change to existing listing)</p> <p>PBS General Schedule</p>	<p>Lennox-Gastaut Syndrome (LGS)</p>	<p>To request listing of fenfluramine as add-on therapy for patients with LGS who are not adequately controlled with at least two other anti-epileptic drugs.</p> <p>Authority Required (Telephone/Online)</p>
<p>FEZOLINETANT</p> <p>Tablet 45 mg</p> <p>Veozal®</p> <p>ASTELLAS PHARMA AUSTRALIA PTY LTD</p> <p>(New PBS listing)</p> <p>PBS General Schedule</p>	<p>Moderate to severe menopause-related vasomotor symptoms (VMS)</p>	<p>Resubmission to request listing of fezolinetant for the treatment of moderate to severe menopause-related VMS for whom menopausal hormone therapy is not suitable.</p> <p>Authority Required (STREAMLINED)</p>

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<p>FUTIBATINIB Tablet 4 mg Lytgobi® TAIHO PHARMA OCEANIA PTY LTD (New PBS listing) PBS General Schedule</p>	<p>Bile duct cancer (cholangiocarcinoma)</p>	<p>Resubmission to request listing of futibatinib for the treatment of patients with locally advanced or metastatic cholangiocarcinoma who have previously progressed on systemic therapy and have a fibroblast growth factor receptor 2 fusion or rearrangement. Authority Required (STREAMLINED)</p>
<p>GIVOSIRAN Solution for injection 189 mg in 1 mL Givlaari® MEDISON PHARMA AUSTRALIA PTY LIMITED (New PBS listing) PBS General Schedule</p>	<p>Acute hepatic porphyria (AHP)</p>	<p>To request listing of givosiran for the treatment of AHP in adults and adolescents aged 12 years and older. This matter was deferred at the July 2025 PBAC Meeting. Authority Required</p>

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<p>GLYCOPYRRONIUM</p> <p>Cream containing glycopyrronium (as bromide) 8 mg per g (2.2 mg per actuation), 50 g</p> <p>Axhidrox®</p> <p>ACTOR PHARMACEUTICALS PTY LTD</p> <p>(New PBS listing)</p> <p>PBS General Schedule</p>	<p>Primary axillary hyperhidrosis</p>	<p>To request listing of glycopyrronium for the treatment of patients aged 18 years and older with severe primary axillary hyperhidrosis.</p> <p>Authority Required (STREAMLINED)</p>
<p>IPTACOPAN</p> <p>Capsule 200 mg</p> <p>Fabhalta®</p> <p>NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED</p> <p>(Change to existing listing)</p> <p>PBS General Schedule</p>	<p>Complement 3 glomerulopathy (C3G)</p>	<p>To request listing of iptacopan for the treatment of adults with C3G with either native kidneys or disease recurrence following a kidney transplant.</p> <p>Authority Required (Written)</p>

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<p>Life Saving Drugs Program (LSDP) medicines for Gaucher disease (type 1)</p> <p>ELIGLUSTAT</p> <p>Capsule containing eliglustat tartrate, 100 mg</p> <p>Cerdelga®</p> <p>IMIGLUCERASE</p> <p>Powder for IV infusion, 400 units</p> <p>Cerezyme®</p> <p>TALIGLUCERASE ALFA</p> <p>Powder for IV infusion, 200 units</p> <p>Elelyso®</p> <p>VELAGLUCERASE ALFA</p> <p>Powder for IV infusion, 400 units</p> <p>Vpriv®</p> <p>Various sponsors</p> <p>(New PBS listing)</p>	<p>Gaucher disease (type 1) (GD1)</p>	<p>Referral from the LSDP Expert Panel seeking the PBAC's advice on whether eliglustat, imiglucerase, taliglucerase alfa, velaglucerase afa, would be cost-effective and suitable for PBS listing for the treatment of GD1. This matter was deferred at the July 2025 PBAC Meeting.</p>

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<p>Life Saving Drugs Program (LSDP) medicine for hereditary tyrosinaemia type 1</p> <p>NITISINONE</p> <p>Capsule 2 mg Capsule 5 mg Capsule 10 mg Capsule 20 mg Oral suspension 4 mg per mL, 90 mL</p> <p>Orfadin®</p> <p>A.MENARINI AUSTRALIA PTY LIMITED</p> <p>(New PBS listing)</p>	<p>Hereditary tyrosinaemia type 1 (HT-1)</p>	<p>Referral from the LSDP Expert Panel seeking the PBAC's advice on whether nitisinone would be cost-effective and suitable for PBS listing for the treatment of HT-1. This matter was deferred at the July 2025 PBAC Meeting.</p>
<p>LURBINECTEDIN</p> <p>Powder for I.V. infusion 2 mg Powder for I.V. infusion 4 mg</p> <p>Zepzelca®</p> <p>SPECIALISED THERAPEUTICS PHARMA PTY LTD</p> <p>(New PBS listing)</p> <p>PBS Section 100 (Efficient Funding of Chemotherapy Program)</p>	<p>Small cell lung cancer (SCLC)</p>	<p>To request listing of lurbinectedin for use in combination with atezolizumab for first line maintenance treatment of extensive-stage SCLC for patients who have not progressed on or after first line induction therapy with atezolizumab, a platinum-based antineoplastic drug, and etoposide.</p> <p>Authority Required (STREAMLINED)</p>

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<p>MIRVETUXIMAB SORAVTANSINE Solution for I.V. infusion 100 mg in 20 mL vial Elahere® ABBVIE PTY LTD (New PBS listing) PBS Section 100 (Efficient Funding of Chemotherapy Program)</p>	<p>Epithelial ovarian, fallopian tube or primary peritoneal cancer</p>	<p>To request listing of mirvetuximab soravtansine for the treatment of high grade epithelial ovarian, fallopian tube or primary peritoneal cancer in patients who have platinum-resistant disease and high folate receptor alpha (FRα) expression. This matter was deferred at the July 2025 PBAC Meeting. Authority Required (Telephone/Online)</p>
<p>OMAVELOXOLONE Capsule 50 mg Skyclarys® BIOGEN AUSTRALIA PTY LTD (New PBS listing) PBS General Schedule</p>	<p>Friedreich's ataxia</p>	<p>Resubmission to request listing of omaxeloxolone for the treatment of Friedreich's ataxia in people aged 16 years and older. Authority Required (Telephone/Online)</p>

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<p>ONASEMNOGENE ABEPARVOVEC</p> <p>Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL</p> <p>Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL</p> <p>Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL</p> <p>Pack containing 3 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL</p> <p>Pack containing 4 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL</p> <p>Pack containing 5 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL</p> <p>Pack containing 6 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL</p> <p>Pack containing 7 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL</p> <p>Pack containing 8 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL</p> <p>Pack containing 9 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL</p> <p>Zolgensma®</p> <p>NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED</p> <p>(Change to existing listing)</p> <p>PBS Section 100 (Highly Specialised Drugs Program)</p>	<p>Spinal muscular atrophy (SMA)</p>	<p>To expand the current PBS listing for onasemnogene abeparvovec for the treatment of SMA to include paediatric patients weighing up to 21 kg.</p> <p>Authority Required (Written)</p>
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<p>OSIMERTINIB Tablet 40 mg Tablet 80 mg Tagrisso® ASTRAZENECA PTY LTD (Change to existing listing) PBS General Schedule To be considered at the September 2025 PBAC meeting*</p>	<p>Non-small cell lung cancer (NSCLC)</p>	<p>Resubmission to request listing of osimertinib for 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. Authority Required (Telephone/Online)</p>

* Please note that consumer comments for OSIMERTINIB (Tagrisso®) will close on 19 August 2025.

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<p>Drug Name, form(s), strength(s) and Sponsor, Submission type, PBS schedule (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p>Drug Type and Use (What is the drug used to treat?)</p>	<p>Listing requested by Sponsor / Purpose of Submission, requested authority level (Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased.)</p>
<p>PEGCETACOPLAN</p> <p>Solution for intravitreal injection 15 mg in 0.1 mL (150 mg per mL)</p> <p>Syfovre®</p> <p>APELLIS AUSTRALIA PTY LTD</p> <p>(New PBS listing)</p> <p>PBS General Schedule</p>	<p>Bilateral geographic atrophy (GA) secondary to age-related macular degeneration (AMD)</p>	<p>To request listing of pegcetacoplan for initial and continuing treatment of bilateral GA secondary to AMD where the treated eye has an intact fovea and central vision is threatened by growth of GA lesions and the non-treated eye does not have an intact fovea.</p> <p>Authority Required (Written or Telephone/Online) initial treatment Authority Required (STREAMLINED) for continuing treatment</p>
<p>PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p>Keytruda®</p> <p>MERCK SHARP & DOHME (AUSTRALIA) PTY LTD</p> <p>(Change to existing listing)</p> <p>PBS Section 100 (Efficient Funding of Chemotherapy Program)</p>	<p>Head and neck squamous cell carcinoma (HNSCC)</p>	<p>To request listing of pembrolizumab for the neoadjuvant treatment (i.e. prior to the main treatment) of patients with resectable locally advanced HNSCC, continued as adjuvant treatment (i.e. after the main treatment) in combination with radiotherapy with or without chemotherapy, and then as a single agent.</p> <p>Authority Required (STREAMLINED)</p>

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<p>POLYETHYLENE GLYCOL 400 WITH PROPYLENE GLYCOL</p> <p>Eye drops 4 mg-3 mg per mL, single dose units 0.8 mL, 28</p> <p>Systane®</p> <p>ALCON LABORATORIES (AUSTRALIA) PTY LTD</p> <p>(New PBS listing)</p> <p>PBS General Schedule</p>	<p>Severe dry eye syndrome</p>	<p>To request listing of a new pack size of Systane (i.e. from 30 x 0.8 mL unit doses to 28 x 0.8 mL unit doses) for the treatment of severe dry eye syndrome.</p> <p>Authority Required (STREAMLINED)</p>
<p>RECOMBINANT ZOSTER VACCINE</p> <p>Powder and suspension for injection (0.5mL)</p> <p>Shingrix®</p> <p>GLAXOSMITHKLINE AUSTRALIA PTY LTD</p> <p>(Change to existing NIP listing)</p>	<p>Prevention of herpes zoster virus</p>	<p>To request a National Immunisation Program listing with age eligibility criteria for non-Indigenous adults reduced from individuals aged 65 years of age and over to individuals aged 60 years of age and over.</p>

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<p>RESPIRATORY SYNCYTIAL VIRUS VACCINE</p> <p>Solution for injection 50 µg in 0.5 mL pre-filled syringe</p> <p>mResvia®</p> <p>MODERNA AUSTRALIA PTY LTD</p> <p>(New NIP listing)</p>	<p>Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)</p>	<p>To request a National Immunisation Program listing for the prevention of lower respiratory tract disease caused by RSV in individuals aged over 75 years and Aboriginal and Torres Strait Islander people aged over 60 years.</p>
<p>RETIFANLIMAB</p> <p>Solution concentrate for I.V. infusion 500 mg in 20 mL</p> <p>Zynyz®</p> <p>SPECIALISED THERAPEUTICS ALIM PTY LTD</p> <p>(New PBS listing)</p> <p>PBS Section 100 (Efficient Funding of Chemotherapy Program)</p>	<p>Merkel cell carcinoma (MCC)</p>	<p>To request listing of retifanimab for the treatment of metastatic or recurrent, locally advanced MCC not amenable to curative surgery or radiation.</p> <p>Authority Required (STREAMLINED)</p>

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<p>RETIFANLIMAB Solution concentrate for I.V. infusion 500 mg in 20 mL Zynyz® SPECIALISED THERAPEUTICS ALIM PTY LTD (New PBS listing) PBS Section 100 (Efficient Funding of Chemotherapy Program)</p>	<p>Squamous cell anal carcinoma (SCAC)</p>	<p>To request listing of retifanlimab for use in combination with carboplatin and paclitaxel for the treatment of inoperable locally recurrent or metastatic SCAC not previously treated with systemic chemotherapy. Authority Required (STREAMLINED)</p>
<p>RISDIPLAM Tablet 5 mg Evrysdi® ROCHE PRODUCTS PTY LTD (New PBS listing) PBS General Schedule</p>	<p>Spinal muscular atrophy (SMA)</p>	<p>To request listing of a new form of risdiplam for the treatment of SMA. Authority Required</p>

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<p>SEMAGLUTIDE</p> <p>Solution for injection 0.25 mg in 0.5 mL single dose pre-filled pen Solution for injection 0.5 mg in 0.5 mL single dose pre-filled pen Solution for injection 1 mg in 0.5 mL single dose pre-filled pen Solution for injection 1.7 mg in 0.75 mL single dose pre-filled pen Solution for injection 2.4mg in 0.75mL single dose pre-filled pen</p> <p>Wegovy®</p> <p>NOVO NORDISK PHARMACEUTICALS PTY. LIMITED</p> <p>(New PBS listing)</p> <p>PBS General Schedule</p>	<p>Established cardiovascular disease (eCVD) with obesity</p>	<p>Resubmission to request listing of semaglutide for the treatment of patients with eCVD living with overweight or obesity.</p> <p>Authority Required (Telephone/Online)</p>

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<p>SPESOLIMAB</p> <p>Solution for injection 300 mg in 2 mL single use pre-filled syringe</p> <p>Spevigo®</p> <p>BOEHRINGER INGELHEIM PTY LTD</p> <p>(New PBS listing)</p> <p>PBS Section 100 (Highly Specialised Drugs Program)</p> <p>WITHDRAWN</p>	<p>Prevention of generalised pustular psoriasis flares</p>	<p>To request listing of spesolimab for the prevention of generalised pustular psoriasis flares in patients aged ≥ 12 years who have a high risk of generalised pustular psoriasis flares due to their background flare history.</p> <p>Authority Required (Telephone/Online)</p>
<p>TAFASITAMAB</p> <p>Powder for I.V. infusion 200 mg</p> <p>Minjuvi®</p> <p>SPECIALISED THERAPEUTICS ALIM PTY LTD</p> <p>(New PBS listing)</p> <p>PBS Section 100 (Efficient Funding of Chemotherapy Program)</p>	<p>Relapsed and/or refractory follicular lymphoma (FL)</p>	<p>To request listing of tafasitamab for use in combination with lenalidomide and rituximab for the treatment of patients with relapsed and/or refractory FL.</p> <p>Authority Required (Telephone/Online)</p>

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TESTOSTERONE Transdermal cream 10 mg per mL, 50 mL AndroFeme 1® LAWLEY PHARMACEUTICALS PTY LTD (New PBS listing) PBS General Schedule	Hypoactive sexual desire dysfunction (HSDD)	To request listing of testosterone for the treatment of HSDD in postmenopausal women that have failed to be treated by appropriate education and correction of modifiable biopsychosocial factors according to the International Society for the Study of Women's Sexual Health process of care. Restricted Benefit
TEZEPELUMAB Solution for injection 210 mg in 1.91 mL single dose pre-filled pen (110 mg per mL) Tezspire® ASTRAZENECA PTY LTD (New PBS listing) PBS Section 100 (Highly Specialised Drugs Program)	Asthma	To request listing for the treatment of severe uncontrolled asthma in patients 12 years and older who have failed to achieve adequate control with optimised asthma therapy. Authority Required (Written)

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<p>TOCILIZUMAB</p> <p>Concentrate for injection 80 mg in 4 mL Concentrate for injection 200 mg in 10 mL Concentrate for injection 400 mg in 20 mL Injection 162 mg in 0.9 mL single use pre-filled pen Injection 162 mg in 0.9 mL single use pre-filled syringe</p> <p>Avtozma®</p> <p>CELLTRION HEALTHCARE AUSTRALIA PTY LTD</p> <p>(New PBS listing)</p> <p>PBS General Schedule PBS Section 100 (Highly Specialised Drugs Program)</p>	<p>Severe active juvenile idiopathic arthritis Severe active rheumatoid arthritis Systemic juvenile idiopathic arthritis Active giant cell arteritis</p>	<p>To request listings of a new tocilizumab biosimilar that mirrors the originator brand's current listings.</p> <p>Authority Required</p>

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<p>TOFERSEN</p> <p>Solution for intrathecal injection 100 mg in 15 mL</p> <p>Qalsody®</p> <p>BIOGEN AUSTRALIA PTY LTD</p> <p>(New PBS listing)</p> <p>PBS Section 100 (Highly Specialised Drugs Program)</p>	<p>Amyotrophic lateral sclerosis (ALS)</p>	<p>To request listing of tofersen for the treatment of ALS associated with a mutation in the superoxide dismutase 1 gene in patients who have not experienced respiratory failure.</p> <p>Authority Required (Telephone/Online)</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>PBS Section 100 (Efficient Funding of Chemotherapy Program)</p>	<p>Gastric or gastroesophageal junction (G/GOJ) cancer</p>	<p>To request listing of trastuzumab deruxtecan for the treatment of metastatic human epidermal growth factor receptor 2-positive (HER2+) G/GOJ cancer following trastuzumab therapy.</p> <p>Authority Required (Telephone/Online)</p>

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<p>TUCATINIB</p> <p>Tablet 50 mg Tablet 150mg</p> <p>Tukysa®</p> <p>PFIZER AUSTRALIA PTY LTD</p> <p>(New PBS listing)</p> <p>General Schedule</p>	<p>Breast cancer</p>	<p>Resubmission to request a listing of tucatinib for use in combination with trastuzumab and capecitabine for the treatment of metastatic (Stage IV) human epidermal growth factor receptor 2 positive breast cancer in patients who have received two prior lines of HER2-directed therapy and have progressed on trastuzumab deruxtecan.</p> <p>Authority Required (STREAMLINED)</p>
<p>VEDOLIZUMAB</p> <p>Powder for injection 300 mg</p> <p>Entyvio®</p> <p>TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD.</p> <p>(Change to existing listing)</p> <p>PBS Section 100 (Highly Specialised Drugs Program)</p>	<p>Severe Crohn disease (CD) Moderate to severe ulcerative colitis (MSUC)</p>	<p>To request a change to the existing listings for vedolizumab (powder for injection 300 mg) for severe CD and MSUC, that is, additional restrictions with increased repeats to allow for dosing every 4 weeks.</p> <p>Authority Required</p>

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<p>WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE</p> <p>Oral powder 400 g, 6 (Renastart)</p> <p>Renastart®</p> <p>VITAFLO AUSTRALIA PTY LIMITED</p> <p>(Change to existing listing)</p> <p>TO BE CONSIDERED AT A FUTURE PBAC MEETING</p>	<p>Chronic Renal Failure</p>	<p>To request a minor formulation change to Renastart for the treatment of chronic renal failure.</p>
<p>ZANUBRUTINIB</p> <p>Tablet 160 mg</p> <p>Brukinsa®</p> <p>BEIGENE AUS PTY LTD</p> <p>(New PBS listing)</p> <p>PBS General Schedule</p>	<p>Mantle cell lymphoma (MCL) Waldenstrom macroglobulinaemia (WM) Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)</p>	<p>To request listing of a new form of zanubrutinib for the treatment of MCL, WM, and CLL or SLL.</p> <p>Authority Required</p>

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<p>Medicines for chronic lymphocytic leukaemia or small lymphocytic lymphoma</p> <p>All brands and strengths</p> <p>Various sponsors</p> <p>(DUSC analysis)</p>	<p>Chronic lymphocytic leukaemia or small lymphocytic lymphoma</p>	<p>To assess the utilisation of PBS listed medicines for the treatment of chronic lymphocytic leukaemia or small lymphocytic lymphoma.</p>
<p>DARATUMUMAB</p> <p>Solution for subcutaneous injection 1,800 mg in 15 mL vial</p> <p>Darzalex SC®</p> <p>JANSSEN-CILAG PTY LTD</p> <p>(DUSC analysis)</p>	<p>Amyloid light-chain (AL) amyloidosis</p>	<p>To assess the utilisation of daratumumab in combination with cyclophosphamide, bortezomib and dexamethasone for the treatment of patients with newly diagnosed AL amyloidosis.</p>

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<p>ELEXACAFTOR, TEZACAFTOR AND IVACAFTOR</p> <p>Pack containing 56 tablets of elexacaftor 100 mg with tezacaftor 50 mg and ivacaftor 75 mg and 28 tablets of ivacaftor 150 mg Pack containing 56 tablets of elexacaftor 50 mg with tezacaftor 25 mg and ivacaftor 37.5 mg and 28 tablets of ivacaftor 75 mg Pack containing 28 sachets elexacaftor 100 mg with tezacaftor 50 mg and with ivacaftor 75 mg and 28 sachets ivacaftor 75 mg Pack containing 28 sachets elexacaftor 80 mg with tezacaftor 40 mg and with ivacaftor 60 mg and 28 sachets ivacaftor 59.5 mg</p> <p>Trikafta®</p> <p>VERTEX PHARMACEUTICALS (AUSTRALIA) PTY. LTD.</p> <p>(DUSC analysis)</p>	<p>Cystic fibrosis</p>	<p>To assess the utilisation of PBS listed elexacaftor with tezacaftor and with ivacaftor, and ivacaftor (Trikafta®) for the treatment of cystic fibrosis.</p>

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<p>CABOTEGRAVIR Suspension for injection 600 mg in 3 mL Apretude® ViiV HEALTHCARE PTY LTD (Review of positive PBAC recommendations not accepted by applicants)</p>	<p>Human immunodeficiency virus (HIV) prevention</p>	<p>To request the PBAC review its September 2023 recommendation that has not yet been accepted by the applicant.</p>
<p>LENACAPAVIR Injection set containing 2 vials lenacapavir sodium solution for injection 463.5 mg in 1.5 mL and 2 disposable syringes Sunlenca® GILEAD SCIENCES PTY LIMITED (Review of positive PBAC recommendations not accepted by applicants)</p>	<p>Human immunodeficiency virus (HIV)</p>	<p>To request the PBAC review its November 2023 recommendation that has not yet been accepted by the applicant.</p>

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<p>PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p>Keytruda®</p> <p>MERCK SHARP & DOHME (Australia) PTY LTD</p> <p>(Review of positive PBAC recommendations not accepted by applicants)</p>	<p>Squamous cell carcinoma</p>	<p>To request the PBAC review its November 2023 recommendation that has not yet been accepted by the applicant.</p>
<p>Ocular lubricants for the treatment of severe dry eye syndrome</p> <p>All forms and strengths</p> <p>All brands</p> <p>Various sponsors</p> <p>(Other matters)</p>	<p>Severe dry eye syndrome</p>	<p>To consider a utilisation analysis of PBS-listed ocular lubricants and the financial estimates of costs to the PBS for potential changes to PBS-listings for ocular lubricants for the treatment of severe dry eye.</p>

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<p>PBAC advice on equitable access to glucagon-like peptide-1 (GLP-1) receptor agonist medicines for the treatment of obesity</p> <p>Various forms and strengths</p> <p>Various brands</p> <p>(Other matters)</p>	<p>Obesity</p>	<p>To provide the PBAC with research findings and to seek its advice on ensuring equitable access to GLP-1 receptor agonist medicines for the treatment of obesity.</p>

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<p>TENOFOVIR DISOPROXIL with EMTRICITABINE</p> <p>Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg</p> <p>CIPLA TENOFOVIR + EMTRICITABINE 300/200</p> <p>CIPLA AUSTRALIA PTY LTD</p> <p>TENOFOVIR/EMTRICITABINE 300/200 APX TENOFOVIR/EMTRICITABINE 300/200 ARX</p> <p>ARROTEX PHARMACEUTICALS PTY LTD</p> <p>Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg</p> <p>TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200</p> <p>ALPHAPHARM PTY LTD</p> <p>Tablet containing tenofovir disoproxil succinate 301 mg with emtricitabine 200 mg</p> <p>TENOFOVIR/EMTRICITABINE SANDOZ 301/200</p> <p>SANDOZ PTY LTD</p> <p>(Other matters)</p>	<p>Pre-exposure prophylaxis (PrEP) against human immunodeficiency virus (HIV) infection</p>	<p>To request the PBAC consider whether increasing the number of repeats in the PBS listing for tenofovir disoproxil+ emtricitabine, for use as HIV PrEP, is appropriate.</p>
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Version 6

Items added or amended

1. SPESOLIMAB (Spevigo®) – Withdrawn

Items added or amended previously

2. AFLIBERCEPT (Eydenzelt®) – Forms amended
3. CABOTEGRAVIR (Apretude®) – Review of positive PBAC recommendations not accepted by applicants – Added
4. CETRORELIX (Femvi®) – PBS schedule amended
5. DESMOPRESSIN (Desmomed) – Added
6. EFGARTIGIMOD ALFA (Vyvgart®) – PBS schedule amended
7. FUTIBATINIB (Lytgobi®) – Added
8. GIVOSIRAN (Givlaari®) – Added
9. LENACAPAVIR (Sunlenca®) – Review of positive PBAC recommendations not accepted by applicants – Added
10. Life Saving Drugs Program (LSDP) medicines for Gaucher disease (type 1) – Added
11. Life Saving Drugs Program (LSDP) medicine for hereditary tyrosinaemia type 1 – Added
12. MIRVETUXIMAB SORAVTANSINE (Elahere®) – Added
13. Ocular lubricants for the treatment of severe dry eye syndrome – Added
14. OSIMERTINIB (Tagrisso®) – To be considered at the September 2025 PBAC meeting
15. PBAC advice on equitable access to glucagon-like peptide-1 (GLP-1) receptor agonist medicines for the treatment of obesity (various brands) – Added
16. PEMBROLIZUMAB (Keytruda®)– Review of positive PBAC recommendations not accepted by applicants – Added
17. RECOMBINANT ZOSTER VACCINE (Shingrix®) – Form and indication amended
18. TENOFOVIR with EMTRICITABINE – Other matters – Added
19. TESTOSTERONE (AndroFeme 1®) – Authority level amended
20. TESTOSTERONE (AndroFeme 1®) – Form amended
21. TRASTUZUMAB DERUXTECAN (Enhertu®) – Added