PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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

Your comments are welcome whether you are a patient, carer, member of the public, health professional or member of a consumer interest group. Comments on new drug submissions, changes to listings and resubmissions and other items on the agenda can now be made through the Office of Health Technology Assessment consultation hub at: https://ohta-consultations.health.gov.au/pbac/.

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.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

- *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 2 – 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.

Category 1, 2 and resubmissions

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.)
ACORAMIDIS Tablet 356 mg Attruby® DKSH HEALTHCARE AUSTRALIA PTY LIMITED New PBS listing PBS General Schedule	Transthyretin amyloid cardiomyopathy (ATTR-CM)	To request listing of acoramidis for the treatment of patients with confirmed ATTR-CM (that is, documented evidence of the presence of the transthyretin precursor protein) and New York Heart Association (NYHA) class I-II heart failure at initiation. Authority Required

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
AFLIBERCEPT Solution for intravitreal injection 11.43 mg in 100 microlitres (114.3 mg per mL) Solution for intravitreal injection 11.43 mg in 100 microlitres (114.3 mg per mL) pre-filled syringe Eylea® BAYER AUSTRALIA LTD Change to existing listing PBS General Schedule	Branch retinal vein occlusion (BRVO) with macular oedema Central retinal vein occlusion (CRVO) with macular oedema	To request listing of the 8 mg strength of Eylea (originator brand of aflibercept) for the treatment of visual impairment due to macular oedema secondary to BRVO or CRVO. Authority Required (Written) for initial treatment Authority Required (STREAMLINED) for continuing treatment
AUMOLERTINIB Tablet 55 mg Velarion® Glenmark Pharmaceuticals (Australia) Pty Limited New PBS listing PBS General Schedule	Non-small cell lung cancer (NSCLC)	To request listing of aumolertinib for the first and second-line treatment of patients with Stage IIIB (locally advanced) or Stage IV (metastatic) NSCLC who have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation. Authority Required (Telephone/Online)

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
BAXDROSTAT Tablet 1 mg Tablet 2 mg Baxfendy® ASTRAZENECA PTY LTD New PBS listing PBS General Schedule	Hypertension	To request listing of baxdrostat for the treatment of uncontrolled and resistant hypertension in adult patients whose blood pressure remains uncontrolled despite treatment with two or more antihypertensive medicines at optimal or maximally tolerated doses. Authority Required (STREAMLINED)
CANNABIDIOL Oral liquid 100 mg per mL, 100 mL Epidyolex® JAZZ PHARMACEUTICALS ANZ PTY LTD Change to existing listing PBS General Schedule	Seizures associated with tuberous sclerosis complex (TSC)	To request listing of cannabidiol as add-on therapy for the treatment of patients with a confirmed diagnosis of TSC experiencing drug-resistant epilepsy, defined as failure to achieve adequate seizure control with at least two appropriately chosen and tolerated anti-seizure medications at therapeutic doses. Authority Required (STREAMLINED)

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
CLESROVIMAB I.M. injection 105 mg in 0.7 mL single dose pre-filled syringe Enflonsia® MERCK SHARP & DOHME (AUSTRALIA) PTY LTD New NIP listing National Immunisation Program (NIP)	Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)	To request a NIP listing of clesrovimab for the prevention of RSV lower respiratory tract disease in: - young infants whose mothers did not receive an RSV vaccine in pregnancy, or who were not vaccinated at least 2 weeks before giving birth; - young infants who are at increased risk of severe RSV disease, regardless of their mother's vaccination status; and - children up to 24 months of age who have medical risk factors for severe RSV disease in their second or subsequent RSV season.
DATOPOTAMAB DERUXTECAN Solution concentrate for I.V. infusion 100 mg in 5 mL Datroway® ASTRAZENECA PTY LTD New PBS listing PBS Section 100 (Efficient Funding of Chemotherapy)	Breast cancer	To request listing of datopotamab deruxtecan for the first-line treatment of patients with unresectable or metastatic triple-negative breast cancer who are not candidates for programmed death ligand-1 [PD-(L)1] inhibitor therapy. Authority Required (STREAMLINED)

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
DROSPIRENONE Pack containing 24 tablets 4 mg and 4 tablets 2.8 mg Slindelle® BESINS HEALTHCARE AUSTRALIA PTY LTD New PBS listing PBS General Schedule	Contraception Endometriosis associated pelvic pain (EAPP)	To request listing of Slindelle for contraception (unrestricted benefit) and for the management of EAPP (streamlined authority). Unrestricted benefit Authority Required (STREAMLINED)
EFGARTIGIMOD ALFA Injection 1000 mg in 5 mL pre-filled syringe Vyvgart® ARGENX AUSTRALIA PTY. LTD. New PBS listing PBS General Schedule	Chronic inflammatory demyelinating polyneuropathy (CIDP)	Resubmission to request listing of efgartigimod alfa for the treatment of adult patients with CIDP who continue to experience significant disability or compromised walking despite an objective response to: - immunoglobulin (Ig) at the TGA-approved maintenance dose (1g/kg every 3 weeks); or - an optimised alternative non-Ig regimen consistent with European Academy of Neurology (EAN) / Peripheral Nerve Society (PNS) guidance, when unable to receive Ig due to not meeting the Blood System for Tracking Authorisations and Reviews (BloodSTAR) clinical efficacy continuation criteria, contraindication or a clinically significant intolerance. Authority Required (Written or Telephone/Online)

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
ENFORTUMAB VEDOTIN Powder for I.V. infusion 20 mg Powder for I.V. infusion 30 mg PADCEV® ASTELLAS PHARMA AUSTRALIA PTY LTD Change to existing listing PBS Section 100 (Efficient Funding of Chemotherapy)	Muscle-invasive bladder cancer (MIBC)	To request listing of enfortumab vedotin in combination with pembrolizumab for the perioperative treatment (i.e. before and after surgery) of patients with non-metastatic MIBC who have agreed to undergo radical cystectomy (bladder removal surgery) and are ineligible for cisplatin-based chemotherapy. Authority Required (STREAMLINED)
EPCORITAMAB Solution concentrate for subcutaneous injection 4 mg in 0.8 mL Solution for subcutaneous injection 48 mg in 0.8 mL Epkinly® ABBVIE PTY LTD Change to existing listing PBS General Schedule PBS Section 100 (Efficient Funding of Chemotherapy)	Relapsed or refractory (R/R) follicular lymphoma (FL)	To request listing of epcoritamab in combination with rituximab and lenalidomide for the treatment of patients with R/R FL who have received one or more prior lines of systemic therapy. Authority Required (STREAMLINED)

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
IVOSIDENIB Tablet 250 mg Tibsovo® SERVIER LABORATORIES (AUST.) PTY. LTD. Change to existing listing PBS General Schedule	Acute myeloid leukaemia (AML)	To request listing of ivosidenib for the treatment of patients with newly diagnosed, isocitrate dehydrogenase-1 (IDH1) mutation positive AML who are not eligible to receive intensive induction chemotherapy. Authority Required (STREAMLINED)
METRELEPTIN Lyophilised powder for injection 3 mg in 0.6 mL Lyophilised powder for injection 5.8 mg in 1.1 mL Lyophilised powder for injection 11.3 mg in 2.2 mL Myalepta® CHIESI AUSTRALIA PTY LTD New PBS listing PBS General Schedule	Lipodystrophy	To request listing of metreleptin (in conjunction with diet and exercise) for the treatment of patients with non-human immunodeficiency virus (HIV)-associated generalised lipodystrophy and partial lipodystrophy who are leptin deficient and have clinically significant and uncontrolled metabolic complications despite best supportive care. Authority Required (STREAMLINED)

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
MIFEPRISTONE AND MISOPROSTOL Pack containing 1 tablet mifepristone 200 mg and 4 tablets misoprostol 200 micrograms MS-2 Step® MS Health Pty Ltd Change to existing listing PBS General Schedule	Management of miscarriage	To request listing of MS-2 Step for the management of miscarriage. The condition must be a missed miscarriage of a pregnancy up to 70 days. Authority Required (STREAMLINED)
NERANDOMILAST Tablet 9 mg Tablet 18 mg Jascayd® BOEHRINGER INGELHEIM PTY LTD New PBS listing PBS General Schedule	Idiopathic pulmonary fibrosis (IPF)	To request listing of nerandomilast for the treatment of patients with IPF who: - are treatment-naïve and initiate nerandomilast as their first pharmacological therapy; - have discontinued nintedanib or pirfenidone due to intolerance, adverse events, or disease progression, and who subsequently receive nerandomilast as monotherapy; and - receive nerandomilast in combination with nintedanib or pirfenidone. Authority Required (Telephone/Online)

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
NERANDOMILAST Tablet 9 mg Tablet 18 mg Jascayd® BOEHRINGER INGELHEIM PTY LTD New PBS listing PBS General Schedule	Progressive pulmonary fibrosis (PPF)	To request listing of nerandomilast for the treatment of patients with PPF who: - are treatment-naïve and initiate nerandomilast as their first pharmacological therapy; - have discontinued nintedanib due to intolerance, adverse events, or disease progression, and who subsequently receive nerandomilast as monotherapy; and - receive nerandomilast in combination with nintedanib. Authority Required (Telephone/Online)
NUSINERSEN Solution for injection 50 mg in 5 mL Solution for injection 28 mg in 5 mL Spinraza® BIOGEN AUSTRALIA PTY LTD New PBS listing PBS Section 100 (Highly Specialised Drugs Program)	Spinal muscular atrophy (SMA)	To request listing of two new strengths of nusinersen for the treatment of patients with SMA for the same populations currently eligible under the existing listings. Authority Required

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® MERCK SHARP & DOHME (AUSTRALIA) PTY LTD Change to existing listing PBS Section 100 (Efficient Funding of Chemotherapy)	Muscle-invasive bladder cancer (MIBC) eligible for cisplatin-based chemotherapy	To request listing of pembrolizumab in combination with enfortumab vedotin for the perioperative treatment (i.e. before and after surgery) of patients with urothelial carcinoma/MIBC who are intending to undergo radical cystectomy (bladder removal surgery) and are eligible for cisplatin-based chemotherapy. Authority Required (STREAMLINED)
PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® MERCK SHARP & DOHME (AUSTRALIA) PTY LTD Change to existing listing PBS Section 100 (Efficient Funding of Chemotherapy)	Muscle-invasive bladder cancer (MIBC) ineligible for cisplatin-based chemotherapy	To request listing of pembrolizumab in combination with enfortumab vedotin for the perioperative treatment (i.e. before and after surgery) of patients with urothelial carcinoma/MIBC who are intending to undergo radical cystectomy (bladder removal surgery) and are ineligible for cisplatin-based chemotherapy. Authority Required (STREAMLINED)

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
PLOZASIRAN Injection 25 mg in 0.5 mL single use pre-filled syringe Redemplo® LUCID HEALTH CONSULTING PTY LTD New PBS listing PBS General Schedule	Familial chylomicronaemia syndrome (FCS)	To request listing of plozasiran (in conjunction with diet and exercise) for the treatment of adult patients with FCS for whom standard triglyceride lowering therapies have been inadequate. Authority Required (Telephone/Online) for initial treatment Authority Required (STREAMLINED) for continuing treatment
RANIBIZUMAB Solution for ocular implant 39.5 mg in 0.395 mL Susvimo® ROCHE PRODUCTS PTY LTD New PBS listing PBS General Schedule	Subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD)	Resubmission to request listing of ranibizumab, for administration via ocular implant, for the treatment of patients with CNV secondary to AMD who have previously demonstrated a response to intravitreal anti-vascular endothelial growth factor (anti-VEGF) therapy. Authority Required (Telephone/Online)

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
RECOMBINANT ZOSTER VACCINE Powder and suspension for injection (0.5mL) Shingrix® GLAXOSMITHKLINE AUSTRALIA PTY LTD Change to existing NIP listing National Immunisation Program (NIP)	Prevention of herpes zoster virus	Resubmission to request an expansion to the NIP listing for recombinant zoster vaccine to include non-indigenous adult patients aged 60 years of age and over, reduced from non-indigenous adult patients aged 65 years of age and over.
SARS-CoV-2 spike protein (mRNA) XBB.1.5 Suspension for injection (0.5mL) mNEXSPIKE® MODERNA AUSTRALIA PTY LTD New NIP listing National Immunisation Program (NIP)	Prevention of coronavirus disease 2019 (COVID-19)	To request a NIP listing of mNEXSPIKE for the prevention of COVID-19 caused by the SARS-CoV-2 virus in adults aged 18 years and older at increased risk of severe COVID-19 disease.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
SEPIAPTERIN Sachet containing oral powder 250 mg Sachet containing oral powder 1000 mg SEPHIENCE® PTC THERAPEUTICS AUSTRALIA PTY LIMITED New PBS listing PBS General Schedule	Hyperphenylalaninaemia (HPA) due to phenylketonuria (PKU)	To request listing of sepiapterin (in combination with a low-phenylalanine diet) for the treatment of patients with HPA due to PKU. Upon initiation of treatment with sepiapterin, patients must have a baseline blood phenylalanine level above 360 micromole per L and be less than one month of age, or patients must have a baseline blood phenylalanine level above 600 micromole per L and be more than one month of age. Authority Required (STREAMLINED)
SOTAGLIFLOZIN Tablet 200 mg Tablet 400 mg Inpefa® VIATRIS PTY LTD New PBS listing PBS General Schedule	Heart failure	To request listing of sotagliflozin in adult patients recently hospitalised for acute decompensated heart failure, regardless of left ventricular ejection fraction (LVEF) and with or without type 2 diabetes. Sotagliflozin is proposed to be initiated during hospitalisation, or within 14 days of discharge, and continued long-term in the community. Authority Required (STREAMLINED)

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
SOTATERCEPT Powder for subcutaneous injection 45 mg (50 mg per mL) Powder for subcutaneous injection 60 mg (50 mg per mL) Winrevair® MERCK SHARP & DOHME (AUSTRALIA) PTY LTD New PBS listing PBS Section 100 (Highly Specialised Drugs Program)	Pulmonary arterial hypertension (PAH)	Resubmission to request listing of sotatercept as add-on therapy for the treatment of adult patients with PAH who have not achieved low risk status according to a validated PAH risk score calculator and have been on stable doses of dual or triple therapy for at least 90 days. The treatment must form part of triple combination therapy consisting of an endothelin receptor antagonist and phosphodiesterase-5 inhibitor, or part of quadruple combination therapy consisting of an endothelin receptor antagonist, phosphodiesterase-5 inhibitor, and selexipag or a prostanoid.
SPARSENTAN Tablet 200 mg Tablet 400 mg Filspari® SEQIRUS (AUSTRALIA) PTY LTD New PBS listing PBS General Schedule	Immunoglobulin A nephropathy (IgAN)	To request listing of sparsentan for the treatment of adult patients with IgAN who have persistent proteinuria (that is, a urine protein excretion ≥ 1.0 g/day) despite at least 12 weeks of stable optimised therapy with an angiotensin-converting enzyme inhibitor (ACEi) and/or angiotensin receptor blocker (ARB). Authority Required (STREAMLINED)

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
TAPINAROF Cream 10 mg per g, 60g Vtama® ORGANON PHARMA PTY LTD New PBS listing PBS General Schedule	Atopic dermatitis	To request listing of tapinarof for the treatment of patients at least 2 years of age with moderate to severe atopic dermatitis who have had an inadequate response to, or for whom topical corticosteroids are not advisable. Authority Required (STREAMLINED)
TEZEPELUMAB Solution for injection 210 mg in 1.91 mL single dose pre-filled pen (110 mg per mL) Tezspire® ASTRAZENECA PTY LTD Change to existing listing PBS Section 100 (Highly Specialised Drugs Program)	Chronic rhinosinusitis with nasal polyps (CRSwNP)	To request listing of tezepelumab for the treatment of adult patients with severe CRSwNP who have received prior NP surgery (or are unsuitable for surgery) and remain inadequately controlled with intra-nasal corticosteroids (unless contraindicated or not tolerated). Authority Required (Written) for initial treatment Authority Required (STREAMLINED) for continuing treatment

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
TORIPALIMAB Solution concentrate for I.V. infusion 240 mg in 6 mL Zytorvi® Dr Reddy's Laboratories (Australia) Pty Ltd Change to existing listing PBS Section 100 (Efficient Funding of Chemotherapy)	Oesophageal squamous cell carcinoma (OSCC)	To request listing of toripalimab, in combination with chemotherapy, for the first-line treatment of patients with unresectable advanced, recurrent, or metastatic OSCC. Authority Required (STREAMLINED)
TRASTUZUMAB DERUXTECAN Powder for I.V. infusion 100 mg Enhertu® ASTRAZENECA PTY LTD Change to existing listing PBS Section 100 (Efficient Funding of Chemotherapy)	Breast cancer	To request listing of trastuzumab deruxtecan for the treatment of patients with human epidermal growth factor receptor 2 (HER2) positive early breast cancer who have pathological residual disease in the breast and/or axillary lymph nodes following neoadjuvant therapy (i.e. therapy given prior to surgery) at a high-risk of disease recurrence. Authority Required (Telephone/Online)

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
VADADUSTAT Tablet 150 mg Tablet 300 mg Vafseo® STADA PHARMACEUTICALS AUSTRALIA PTY LIMITED New PBS listing PBS General Schedule PBS Section 100 (Highly Specialised Drugs Program)	Anaemia associated with intrinsic renal disease	To request listing of vadadustat for the treatment of adult patients with anaemia associated with intrinsic renal disease who require a transfusion, have a haemoglobin level of less than 100 g/L and are undergoing dialysis. Authority Required (STREAMLINED)

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

Other items

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.)
DAROLUTAMIDE 300 mg tablet, 112 Nubeqa® Bayer Australia Ltd (Sub-committee report DUSC analysis)	Metastatic castration sensitive carcinoma of the prostate.	To review the utilisation of darolutamide for the treatment of metastatic castration sensitive carcinoma of the prostate.
DURVALUMAB 120 mg/2.4 mL injection, 2.4 mL vial 500 mg/10 mL injection, 10 mL vial Imfinzi® AstraZeneca Pty Ltd (Sub-committee report DUSC analysis)	Locally advanced, metastatic or recurrent biliary tract cancer (intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, and gallbladder cancer).	To assess the utilisation of PBS listed durvalumab for locally advanced, metastatic or recurrent biliary tract cancer (intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, and gallbladder cancer).

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
SEMAGLUTIDE 1.34 mg/mL injection, 1 x 3 mL pen device 0.68 mg/mL injection, 1 x 3 mL pen device Ozempic® Novo Nordisk Pharmaceuticals Pty. Limited DULAGLUTIDE 1.5 mg/0.5 mL injection, 4 x 0.5 mL pen devices Trulicity® Eli Lilly Australia Pty Ltd (Sub-committee report DUSC analysis)	Diabetes mellitus type 2	To review the use of glucagon-like peptide-1 (GLP-1) medicines for type 2 diabetes, including assessing whether the 1 June 2024 restriction changes have been effective in limiting GLP-1 use to the recommended population.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

Category 3, 4, and committee secretariat submissions

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.)
ADALIMUMAB Injection 20 mg in 0.2 mL pre-filled syringe Injection 40 mg in 0.4 mL pre-filled syringe Injection 40 mg in 0.4 mL pre-filled pen Injection 80 mg in 0.8 mL pre-filled pen Amgevita® AMGEN AUSTRALIA PTY LIMITED Change to existing listing PBS General Schedule	Immune-mediated inflammatory disease	To request a broad listing of Amgevita (for the higher concentration forms that were recommended by the PBAC at its March 2026 meeting) for the treatment of immune-mediated inflammatory disease. Authority Required (STREAMLINED)
APIXABAN Oral suspension 1.25 mg per mL, 150 mL Axoran® ACTOR PHARMACEUTICALS PTY LTD New PBS listing PBS General Schedule	Prevention of stroke or systemic embolism Prevention of recurrent venous thromboembolism Deep vein thrombosis Pulmonary embolism Prevention of venous thromboembolism	To request a new oral liquid suspension form of apixaban for the same indications as the tablet form of apixaban. To request that apixaban oral liquid suspension be considered as an exempt item under section 84AH of the National Health Act 1953. Where a pharmaceutical item is determined to be an exempt item, that pharmaceutical item is excluded from fifteen year Anniversary Price, first new brand and price disclosure reductions. Exempt items are not exempt from five and ten year Anniversary Price reductions. Authority Required (STREAMLINED)

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
ARIPIPRAZOLE I.M. injection (modified release) 720 mg (as monohydrate) in 2.4 mL pre-filled syringe I.M. injection (modified release) 960 mg (as monohydrate) in 3.2 mL pre-filled syringe Abilify Asimtufii® LUNDBECK AUSTRALIA PTY LTD Change to existing listing PBS General Schedule	Schizophrenia	To request a change to the existing listing of Abilify Asimtufii for the treatment of schizophrenia to remove the requirement for prior treatment with monthly long-acting injectable aripiprazole before initiating the two monthly formulation in order to align with the current Therapeutic Goods Administration (TGA)-approved Product Information (PI). Authority Required (STREAMLINED)
AVACINCAPTAD PEGOL Solution for intravitreal injection 2 mg in 0.1 mL (20 mg per mL) Izervay® ASTELLAS PHARMA AUSTRALIA PTY LTD New PBS listing PBS General Schedule	Geographic atrophy (GA) secondary to age-related macular degeneration (AMD)	To consider the sponsor's revised proposal for listing avacincaptad pegol for the treatment of patients with GA secondary to AMD who have an intact fovea and where central vision is threatened by GA lesion growth. This item was previously recommended by the PBAC at its March 2026 meeting. Authority Required (Written) Authority Required (STREAMLINED) for continuing treatment

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
BUDESONIDE Oral suspension 0.2 mg per 1 mL, 165 mL Jorveza® DR FALK PHARMA AUSTRALIA PTY LTD New PBS listing PBS General Schedule	Eosinophilic oesophagitis	To request a new oral suspension form of budesonide (BOS) for the treatment of patients with eosinophilic oesophagitis. The proposed restrictions for BOS are based on those for budesonide orally disintegrating tablet (BOT) but with a number of changes, some of which are requested to flow on to BOT. One such change is the removal of the requirement for a biopsy / histologic assessment within 12 weeks of applying for treatment. Authority Required (STREAMLINED)
CANNABIDIOL Oral liquid 100 mg per mL, 100 mL Epidyolex® JAZZ PHARMACEUTICALS ANZ PTY LTD Change to existing listing PBS General Schedule	Dravet syndrome (DS) Lennox-Gastaut syndrome (LGS)	To request an increase in the maximum quantity per prescription of Epidyolex from one bottle to five bottles when used in the treatment of seizures associated with DS and LGS. Authority Required (STREAMLINED)

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
DENOSUMAB Injection 60 mg in 1 mL pre-filled syringe Denolia® Deskelta® Injection 120 mg in 1.7 mL pre-filled syringe Dexeva® Dostiva® ACCORD HEALTHCARE PTY. LTD. New PBS listing PBS General Schedule	Osteoporosis Bone metastases Giant cell tumour of bone	To request listing of four new denosumab biosimilars that mirror their respective originator brand's current listings. Authority Required (STREAMLINED)

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
DURVALUMAB Solution concentrate for I.V. infusion 120 mg in 2.4 mL Solution concentrate for I.V. infusion 500 mg in 10 mL Imfinzi® ASTRAZENECA PTY LTD Change to existing listing PBS Section 100 (Efficient Funding of Chemotherapy)	Non-small cell lung cancer (NSCLC)	To request a change to the existing listing of durvalumab for the treatment of unresectable stage III NSCLC to remove the requirement for a patient to be untreated with immunotherapy at commencement of durvalumab. Authority Required (STREAMLINED)
EVOLOCUMAB Injection 140 mg in 1 mL single use pre-filled pen Repatha® AMGEN AUSTRALIA PTY LIMITED Change to existing listing PBS General Schedule	Non-familial hypercholesterolaemia Familial heterozygous hypercholesterolaemia Familial homozygous hypercholesterolaemia	To request a new deed and Risk Sharing Arrangement (RSA) for evolocumab (and inclisiran) to cover the period 1 May 2026 to 30 April 2031. Authority Required (STREAMLINED)

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
FREMANEZUMAB Solution for injection 225 mg in 1.5 mL single dose pre-filled syringe Solution for injection 225 mg in 1.5 mL single dose auto-injector Ajovy® TEVA PHARMA AUSTRALIA PTY LTD Change to existing listing PBS General Schedule	Treatment-resistant migraine	To request listing of fremanezumab for treatment-resistant migraine to enable 3-monthly dosing in addition to the existing monthly dosing. This item was previously recommended by the PBAC at its March 2022 meeting. Authority Required (STREAMLINED)
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS Sachets containing oral powder 40 g, 30 (Camino Pro Bettermilk) Camino Pro Bettermilk® CORTEX HEALTH PTY LTD Change to existing listing PBS General Schedule	Phenylketonuria (PKU)	To inform the PBAC of a minor formulation change to Camino Pro Bettermilk for the treatment of children and adults with PKU. Restricted Benefit

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS Sachets containing oral powder 15 g, 30 (PKU Build 10) PKU Build 10® CORTEX HEALTH PTY LTD Change to existing listing PBS General Schedule	Phenylketonuria (PKU)	To inform the PBAC of a minor formulation change to PKU Build 10 for the treatment of children and adults with PKU. Restricted Benefit
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS Sachets containing oral powder 15 g, 30 (PKU Build 20) PKU Build 20® CORTEX HEALTH PTY LTD Change to existing listing PBS General Schedule	Phenylketonuria (PKU)	To inform the PBAC of a minor formulation change to PKU Build 20 for the treatment of children and adults with PKU. Restricted Benefit

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS Oral liquid 250 mL, 30 (PKU Glytactin RTD 15) PKU Glytactin RTD 15® CORTEX HEALTH PTY LTD Change to existing listing PBS General Schedule	Phenylketonuria (PKU)	To inform the PBAC of a minor formulation change to PKU Glytactin RD 15 for the treatment of children and adults with PKU. Restricted Benefit
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS Oral liquid 250 mL, 30 (PKU Glytactin RTD 15 Lite) PKU Glytactin RTD 15 Lite® CORTEX HEALTH PTY LTD Change to existing listing PBS General Schedule	Phenylketonuria (PKU)	To inform the PBAC of a minor formulation change to PKU Glytactin RD 15 Lite for the treatment of children and adults with PKU. Restricted Benefit

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS Sachets containing oral powder 20 g, 60 (PKU Restore) PKU Restore® CORTEX HEALTH PTY LTD Change to existing listing PBS General Schedule	Phenylketonuria (PKU)	To inform the PBAC of a minor formulation change to PKU Restore for the treatment of children and adults with PKU. Restricted Benefit
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACID FORMULA WITH VITAMINS, MINERALS, AND LOW IN TYROSINE AND PHENYLALANINE Sachets containing oral powder 31 g, 30 (Tylactin Build 20) Tylactin Build 20® CORTEX HEALTH PTY LTD Change to existing listing PBS General Schedule	Tyrosinaemia	To inform the PBAC of a minor formulation change to Tylactin Build 20 for the treatment of children and adults with tyrosinaemia. Restricted Benefit

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS Oral liquid 250 mL, 30 (Tylactin RTD) Tylactin RTD® CORTEX HEALTH PTY LTD Change to existing listing PBS General Schedule	Tyrosinaemia	To inform the PBAC of a minor formulation change to Tylactin RTD for the treatment of children and adults with tyrosinaemia. Restricted Benefit

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
HYALURONIC ACID Eye drops containing sodium hyaluronate 0.1 mg per mL, 10 mL Opticalm Intensive® Eye drops containing sodium hyaluronate 0.21 mg per mL, 10 mL Opticalm Fast® Eye drops containing sodium hyaluronate 0.4 mg per mL, 10 mL Opticalm Ultra® ARO INVESTMENTS PTY LIMITED New PBS listing PBS General Schedule	Severe dry eye syndrome	To request listing of three new brands of hyaluronate sodium eye drops for the treatment of severe dry eye syndrome. Authority Required (STREAMLINED)

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
IMIQUIMOD Cream 50 mg per g, 250 mg single use sachets, 12 Aldara® Cream 50 mg per g, 2 g, 2 Aldara Pump® INOVA PHARMACEUTICALS (AUSTRALIA) PTY LIMITED Change to existing listing PBS General Schedule	Superficial basal cell carcinoma (BCC)	To request a change in authority level for imiquimod for the treatment of superficial BCC from Authority Required (Telephone/Online) to Authority Required (STREAMLINED). Authority Required (STREAMLINED)
LENIOLISIB Tablet 70 mg Joenja® PHARMING AUSTRALIA PTY LTD New PBS listing PBS Section 100 (Highly Specialised Drugs Program)	Activated PI3K delta syndrome (APDS)	To consider the sponsor's revised proposal for listing leniolisib for the treatment of symptomatic APDS in adults and adolescents aged 12 years and older. This item was previously recommended by the PBAC at its July 2025 meeting. The revised proposal specifically requests that the PBAC reconsider its recommendation for a Section 100 listing and instead recommend funding via the Life Saving Drugs Program (LSDP). Authority Required (Written) for initial treatment Authority Required (Telephone/Online) for continuing treatment

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
PEMBROLIZUMAB Solution for subcutaneous injection containing pembrolizumab 395 mg in 2.4 mL vial Solution for subcutaneous injection containing pembrolizumab 790 mg in 4.8 mL vial Keytruda SC® MERCK SHARP & DOHME (AUSTRALIA) PTY LTD New PBS listing PBS General Schedule PBS Section 100 (Efficient Funding of Chemotherapy)	Cancer	To request listing of a new subcutaneous form of pembrolizumab (in two different strengths) under the same circumstances and for the same indications as the currently listed intravenous form. Authority Required (STREAMLINED)
RANIBIZUMAB Solution for intravitreal injection 1.65 mg in 0.165 mL pre-filled syringe Raniviz® ACTOR PHARMACEUTICALS PTY LTD New PBS listing PBS General Schedule	Branch retinal vein occlusion with macular oedema Central retinal vein occlusion with macular oedema Proliferative diabetic retinopathy and/or diabetic macular oedema Subfoveal choroidal neovascularisation	To request listing of a new ranibizumab biosimilar that mirrors the originator brand's current listings. Authority Required (STREAMLINED)

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
RANIBIZUMAB 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 Solentis® Simulara® GENERIC HEALTH PTY LTD New PBS listing PBS General Schedule	Branch retinal vein occlusion with macular oedema Central retinal vein occlusion with macular oedema Proliferative diabetic retinopathy and/or diabetic macular oedema Subfoveal choroidal neovascularisation	To request listing of two new ranibizumab biosimilars that mirror the originator brand's current listings. Authority Required for initial treatment Authority Required (STREAMLINED) for continuing treatment
SECUKINUMAB Injection 150 mg in 1 mL pre-filled pen Injection 300 mg in 2 mL pre-filled pen Cosentyx® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED Change to existing listing PBS General Schedule	Severe chronic plaque psoriasis Ankylosing spondylitis Severe psoriatic arthritis Non-radiographic axial spondyloarthritis Moderate to severe hidradenitis suppurativa	To request a change to all existing listings of secukinumab for all indications to allow prescribing by nurse practitioners. Authority Required

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
SEMAGLUTIDE 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 Wegovy® NOVO NORDISK PHARMACEUTICALS PTY. LIMITED New PBS listing PBS General Schedule	Established atherosclerotic cardiovascular disease (eASCVD) with obesity	To consider the sponsor's revised proposal for listing semaglutide for the treatment of adult patients with eASCVD, defined as a documented history of prior myocardial infarction or stroke, or symptomatic peripheral arterial disease, with a body mass index (BMI) greater than or equal to 35 kg/m^2. This item was previously recommended by the PBAC at its November 2025 meeting. Authority Required (Telephone/Online)

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2026 PBAC MEETING

Closing date for consumer consultation 16 September 2026

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.)
TAFAMIDIS Capsule 61 mg Vyndamax® PFIZER AUSTRALIA PTY LTD Change to existing listing PBS General Schedule	Transthyretin amyloid cardiomyopathy (ATTR-CM)	To request revision of the previously estimated utilisation of tafamidis for the treatment of ATTR-CM, specifically, an increase to the subsidisation caps for the current Risk Sharing Arrangement (RSA). This item was last considered at the March 2026 PBAC meeting. Authority Required (Written or Telephone/Online) for initial treatment Authority Required (Telephone/Online) for continuing treatment
ZOLBETUXIMAB Powder for I.V. infusion 300 mg (6 mg per mL) Vyloy® ASTELLAS PHARMA AUSTRALIA PTY LTD New PBS listing PBS Section 100 (Efficient Funding of Chemotherapy)	Gastric or gastroesophageal junction (G/GOJ) cancer	To request listing of a new form of zolbetuximab (in combination with platinum-based chemotherapy plus a fluoropyrimidine drug) for the first-line treatment of patients with locally advanced, unresectable or metastatic epidermal growth factor receptor 2-negative G/GOJ cancer. The 100 mg injection vial was previously recommended by the PBAC at its September 2025 meeting. Authority Required (STREAMLINED)