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

Closing date for consumer consultation 21 January 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

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.)
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 (New PBS listing) PBS General Schedule PBS Section 100 (Highly Specialised Drugs Program)	Crohn disease Ulcerative colitis Active juvenile idiopathic arthritis Complex refractory fistulising Crohn disease Active rheumatoid arthritis Psoriatic arthritis Ankylosing spondylitis Chronic plaque psoriasis Hidradenitis suppurativa	To request listing of four new higher concentration forms of the Amgevita biosimilar brand of adalimumab that mirror the current PBS-listed adalimumab brands with the same strengths and forms. Authority Required

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ADALIMUMAB Injection 20 mg in 0.2 mL single use pre-filled syringe Yuflyma® CELLTRION HEALTHCARE AUSTRALIA PTY LTD (New PBS listing) PBS General Schedule PBS Section 100 (Highly Specialised Drugs Program)	Moderate to severe ulcerative colitis Severe juvenile idiopathic arthritis Severe chronic plaque psoriasis Severe Crohn disease Vision-threatening non-infectious uveitis	To request listing of a new form of the Yuflyma biosimilar brand of adalimumab that mirrors the originator brand's current listings with the same form (20 mg in 0.2 mL pre-filled syringe). Authority Required

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ADALIMUMAB Injection 20 mg in 0.2 mL pre-filled syringe Injection 20 mg in 0.4 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 40 mg in 0.8 mL pre-filled syringe Injection 40 mg in 0.8 mL pre-filled pen Injection 80 mg in 0.8 mL pre-filled syringe Injection 80 mg in 0.8 mL pre-filled pen Various brands Various sponsors INFLIXIMAB Powder for I.V. infusion 100 mg Various brands Various sponsors (Change to existing listing)	Crohn disease Ulcerative colitis	To seek PBAC advice on the appropriateness of the current prior-therapy requirements specified in the PBS listings for adalimumab and infliximab for the treatment of paediatric patients with Crohn disease and ulcerative colitis, and to seek advice on matters relating to the administration of these PBS listings.

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ADRENALINE (EPINEPHRINE) Nasal spray device 1 mg in 1 actuation Nasal spray device 2 mg in 1 actuation Neffy® SEQIRUS (AUSTRALIA) PTY LTD (New PBS listing) PBS General Schedule	Acute allergic reaction with anaphylaxis	To request listing of a new form of adrenaline (epinephrine) for the emergency treatment of acute severe allergic reactions in children or adults at significant risk of anaphylaxis. Authority Required (Telephone/Online)
ALECTINIB Capsule 150 mg Alecensa® ROCHE PRODUCTS PTY LTD (Change to existing listing) PBS General Schedule	Non-small cell lung cancer (NSCLC)	To consider the sponsor's proposal for listing alectinib for adjuvant treatment of adult patients following tumour resection of anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC). This item was previously recommended by the PBAC at its May 2025 meeting. To consider consumer input regarding re-treatment with an ALK inhibitor in the metastatic setting following adjuvant alectinib treatment. Authority Required (Telephone/Online)

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AMIVANTAMAB Solution concentrate for I.V. infusion 350 mg in 7 mL Rybrevant® JANSSEN-CILAG PTY LTD (Change to existing listing) PBS Section 100 (Efficient Funding of Chemotherapy Program)	Non-small cell lung cancer (NSCLC)	To request listing of amivantamab for use in combination with platinum-based chemotherapy for the treatment of adult patients with locally advanced or metastatic NSCLC with an epidermal growth factor receptor (EGFR) gene mutation, whose condition has progressed on or after treatment with osimertinib. Authority Required (Telephone/Online)
ASCIMINIB Tablet 20 mg Tablet 40 mg Scemblix® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED (Change to existing listing) PBS General Schedule WITHDRAWN	Chronic myeloid leukaemia (CML)	To request listing of asciminib for the treatment of adult patients with newly diagnosed CML in chronic phase. Authority Required (Telephone/Online) for initial treatment Authority Required (STREAMLINED) for continuing treatment

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ASCIMINIB Tablet 20 mg Tablet 40 mg Scemblix® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED (Change to existing listing) PBS General Schedule	Chronic myeloid leukaemia (CML)	To request a change to all listings of asciminib for the treatment of CML to allow prescribing by nurse practitioners. Authority Required
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 request listing of avacincaptad pegol for the treatment of adult patients with GA secondary to AMD, who have an intact fovea and where central vision is threatened by GA lesion growth. Authority Required (Written or Telephone/Online) for initial treatment Authority Required (STREAMLINED) for continuing treatment

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BIRCH TRITERPENES Gel containing 100 mg per 1 g, 23.4 g Filsuvez® CHIESI AUSTRALIA PTY LTD (New PBS Listing) PBS General Schedule TO BE CONSIDERED AT A FUTURE PBAC MEETING	Dystrophic or junctional epidermolysis bullosa (EB)	To request listing of birch triterpenes for the treatment of patients aged 6 months and older with partial thickness skin wounds caused by dystrophic or junctional EB. Authority Required (Written) for initial treatment Authority Required (Telephone/Online) for continuing treatment
BUROSUMAB Solution for injection 10 mg in 1 mL Solution for injection 20 mg in 1 mL Solution for injection 30 mg in 1 mL Crysvita® KYOWA KIRIN AUSTRALIA PTY LTD (Change to existing listing) PBS Section 100 (Highly Specialised Drugs Program)	Tumour induced osteomalacia (TIO)	To request listing of burosumab for the treatment of adult and paediatric patients with TIO, presenting with hypophosphataemia due to fibroblast growth factor 23 (FGF23), where phosphaturic mesenchymal tumours cannot be curatively resected or localised. Authority Required

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CANAKINUMAB Solution for injection 150 mg in 1 mL Ilaris® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED (New PBS listing) PBS Section 100 (Highly Specialised Drugs Program)	Colchicine-resistant or intolerant Familial Mediterranean Fever (crFMF)	To request listing of canakinumab for the treatment of paediatric crFMF patients who continue canakinumab treatment into adulthood (provided they initiated canakinumab treatment before turning 18 years of age). Authority Required (Telephone/Online)
CANNABIDIOL Oral liquid 100 mg per mL, 100 mL Epidyolex® JAZZ PHARMACEUTICALS ANZ PTY LTD (Change to existing listing) PBS General Schedule	Severe myoclonic epilepsy in infancy (Dravet syndrome)	To request an amendment to the restriction level from Authority Required (Telephone/Online) to Authority Required (STREAMLINED) for the treatment of Dravet syndrome. The submission also requested amendments to the treatment criteria to allow prescribing by a paediatrician without the need for consultation with a neurologist, and continuation of therapy by a general practitioner with a paediatrician. Authority Required (STREAMLINED)

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CICLOSPORIN Eye drops containing ciclosporin 1 mg per mL, 2 mL Vevye® AFT PHARMACEUTICALS (AU) PTY LTD (New PBS Listing) PBS General Schedule	Dry eye disease with keratitis	To request listing of a new form of ciclosporin eye drops for the treatment of dry eye disease with keratitis in adult patients whose condition has not been adequately controlled by monotherapy with an artificial tears substitute. Authority Required (Telephone/Online)
DUPILUMAB Injection 300 mg in 2 mL single dose pre-filled syringe Injection 300 mg in 2 mL single dose pre-filled pen Dupixent® SANOFI-AVENTIS AUSTRALIA PTY LTD (Change to existing listing) PBS General Schedule	Chronic obstructive pulmonary disease (COPD)	To request listing of dupilumab for use as add-on maintenance treatment for uncontrolled COPD in adult patients with raised blood eosinophils and on a stable combination of an inhaled corticosteroid (ICS), a long-acting beta2-agonist (LABA), and a long-acting muscarinic antagonist (LAMA). Authority Required (Telephone/Online)

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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 Program)	Gastric cancer (GC) or gastro-oesophageal junction cancer (GOJC)	To request listing of durvalumab for the perioperative treatment (i.e. before and after surgery) of adult patients with GC or GOJC who are eligible for neoadjuvant FLOT (fluorouracil, leucovorin, oxaliplatin, docetaxel) chemotherapy (i.e. eligible for FLOT chemotherapy given prior to surgery). Authority Required (Telephone/Online)
EDARAVONE Solution concentrate for I.V. infusion 30 mg in 20 mL Radicava® TEVA PHARMA AUSTRALIA PTY LTD (Change to existing listing) PBS Section 100 (Highly Specialised Drugs Program) To be considered prior to the March 2026 PBAC meeting	Amyotrophic lateral sclerosis (ALS)	To request a change to the existing listing of edaravone for the initial treatment of ALS, to allow initiation of treatment outside public or private hospital settings. Authority Required (Telephone/Online)

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EFGARTIGIMOD ALFA Injection 1000 mg in 5 mL pre-filled syringe Vyvgart® ARGENX AUSTRALIA PTY. LTD. (New PBS listing) PBS General Schedule	Generalised myasthenia gravis (gMG)	To request listing of a pre-filled syringe form of efgartigimod alfa for the initial and continuing treatment of adult patients with gMG who are anti-acetylcholine receptor antibody positive. Authority Required (Telephone/Online)
EFGARTIGIMOD ALFA Solution for subcutaneous injection 1000 mg in 5.6 Injection 1000 mg in 5 mL pre-filled syringe Vyvgart® ARGENX AUSTRALIA PTY. LTD. (Change to existing listing) PBS General Schedule	Chronic inflammatory demyelinating polyneuropathy (CIDP)	To request listing of efgartigimod alfa for the treatment of adult patients with progressive or relapsing active CIDP who have had an inadequate response to immunoglobulin (Ig) alone or in combination with another therapeutic treatment, or are refractory to Ig, or have an intolerance or contraindication to Ig. Authority Required (Written or Telephone/Online)

ENOXAPARIN Injection containing enoxaparin sodium 20 mg (2,000 I.U. anti-Xa) in 0.2 mL pre-filled syringe Injection containing enoxaparin sodium 40 mg (4,000 I.U. anti-Xa) in 0.4 mL pre-filled syringe Injection containing enoxaparin sodium 60 mg (6,000 I.U. anti-Xa) in 0.6 mL pre-filled syringe Injection containing enoxaparin sodium 80 mg (8,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe Injection containing enoxaparin sodium 100 mg (10,000 I.U. anti-Xa) in 1 mL pre-filled syringe Injection containing enoxaparin sodium 120 mg (12,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe Injection containing enoxaparin sodium 150 mg (15,000 I.U. anti-Xa) in 1 mL pre-filled syringe Clexane® Safety-Lock Clexane® Forte Safety-Lock SANOFI-AVENTIS AUSTRALIA PTY LTD (Other matters) PBS General Schedule WITHDRAWN	Prevention and treatment of thrombo-embolic disorders Haemodialysis	To request listing of Clexane with a new safety system, consistent with the existing PBS listings for Clexane Safety-Lock and Clexane Forte Safety-Lock. Restricted Benefit

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ENZALUTAMIDE Capsule 40 mg Xtandi® ASTELLAS PHARMA AUSTRALIA PTY LTD (Change to existing listing) PBS General Schedule	Non-metastatic hormone sensitive prostate cancer (nmHSPC)	Resubmission to request listing of enzalutamide for use with concurrent androgen deprivation therapy in patients with nmHSPC with biochemical recurrence at high-risk for metastasis. Authority Required (Telephone/Online)
GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE Sachets containing oral powder 40 g, 30 (PKU GMPro Delight) PKU GMPro® Delight NUTRICIA AUSTRALIA PTY LIMITED (New PBS listing) PBS General Schedule	Phenylketonuria (PKU)	To request listing of PKU GMPro Delight for the dietary management of PKU in children (from 3 years of age) and adults. Restricted Benefit

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INCOBOTULINUMTOXINA Lyophilised powder for injection 100 units Xeomin® MERZ AUSTRALIA PTY LTD (Change to existing listing) PBS Section 100 (Botulinum Toxin Program)	Moderate to severe spasticity of the lower limb in adults following an acute event	To request listing of incobotulinumtoxinA (Xeomin®) for the treatment of moderate to severe spasticity of the lower limb in adults following an acute event. Authority Required (STREAMLINED)
INOTUZUMAB OZOGAMICIN Powder for I.V. infusion 1 mg Besponsa® PFIZER AUSTRALIA PTY LTD (Other matters) PBS Section 100 (Efficient Funding of Chemotherapy Program)	Acute lymphoblastic leukaemia (ALL)	To seek PBAC advice on the termination of the Risk Sharing Arrangement (RSA) component of the Deed of agreement for inotuzumab ozogamicin for the treatment of acute lymphoblastic leukaemia (ALL). Authority Required

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LANREOTIDE Injection 60 mg (as acetate) in single dose pre-filled syringe Injection 90 mg (as acetate) in single dose pre-filled syringe Injection 120 mg (as acetate) in single dose pre-filled syringe Lacreo SUN PHARMA ANZ PTY LTD (New PBS listing) PBS Section 100 (Highly Specialised Drugs Program)	Acromegaly Functional carcinoid tumour Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)	To request listing of a new brand of lanreotide for the treatment of three conditions: 1. Patients with acromegaly when the circulating levels of growth hormone and IGF-1 remain abnormal after surgery and/or radiotherapy or in patients who are dopamine agonist treatment refractory; 2: Patients with symptoms of carcinoid syndrome associated with carcinoid tumours; and 3: Adult patients with unresectable locally advanced or metastatic GEP-NETs. Authority Required (STREAMLINED)
LONCASTUXIMAB TESIRINE Powder for I.V. infusion 10 mg Zynlonta® SWEDISH ORPHAN BIOVITRUM PTY LTD (New PBS listing) PBS Section 100 (Efficient Funding Of Chemotherapy)	Diffuse large B-cell lymphoma (DLBCL)	To request listing of loncastuximab tesirine for the treatment of adult patients with relapsed or refractory DLBCL who have received two or more prior lines of therapy. Authority Required (Telephone/Online) for initial treatment Authority Required (STREAMLINED) for continuing treatment

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MEPOLIZUMAB Injection 100 mg in 1 mL single dose pre-filled pen Nucala® GLAXOSMITHKLINE AUSTRALIA PTY LTD (Change to existing listing) PBS Section 100 (Highly Specialised Drugs Program)	Chronic obstructive pulmonary disease (COPD)	To request listing of mepolizumab for use in combination with an inhaled corticosteroid (ICS), a long-acting beta-agonist (LABA), and a long-acting muscarinic antagonist (LAMA) for the treatment of adult patients with COPD characterised by an eosinophilic phenotype who continue to experience exacerbations. Authority Required (Written)
NEMOLIZUMAB Powder for injection containing nemolizumab 30 mg with diluent in pre-filled dual-chamber pen Nemluvio® GALDERMA AUSTRALIA PTY LTD (New PBS listing) PBS General Schedule	Atopic dermatitis	Resubmission to request listing of nemolizumab for the treatment of moderate to severe atopic dermatitis in patients aged 12 years and older who are eligible for systemic therapy. Authority Required (Telephone/Online)

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NIVOLUMAB Solution for subcutaneous injection 600 mg in 5 mL Opdivo® BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD (New PBS listing) PBS General Schedule PBS Section 100 (Efficient Funding of Chemotherapy Program)	Malignant melanoma Non-Small Cell Lung Cancer (NSCLC) Renal Cell Carcinoma (RCC) Squamous Cell Carcinoma of the Head and Neck (SCCHN) Urothelial Carcinoma (UC) Oesophageal / Gastro-oesophageal cancers (OC/GC)	To request listing of a new strength and form of nivolumab for the existing PBS-listed indications, except where nivolumab is administered every three weeks in combination with ipilimumab. Authority Required (Telephone/Online) Authority Required (STREAMLINED)
OBINUTUZUMAB Solution for I.V. infusion 1000 mg in 40 mL Gazyva® ROCHE PRODUCTS PTY LTD (Change to existing listing) PBS Section 100 (Highly Specialised Drugs Program)	Lupus nephritis	To request listing of obinutuzumab for the treatment of adult patients with a confirmed diagnosis of active class III or IV lupus nephritis with or without class V who are receiving standard therapy with mycophenolate and corticosteroids. Authority Required (Telephone/Online)

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ODEVIXIBAT Capsule 200 micrograms Capsule 400 micrograms Capsule 600 micrograms Capsule 1200 micrograms Bylvay® IPSEN PTY LTD (Change to existing listing) PBS General Schedule	Alagille syndrome (ALGS)	To request listing of odevixibat for the treatment of cholestatic pruritis in ALGS in patients aged 6 months and older. Authority Required
OMALIZUMAB Injection 75 mg in 0.5 mL single dose pre-filled pen Injection 150 mg in 1 mL single dose pre-filled pen Omlyclo® CELLTRION HEALTHCARE AUSTRALIA PTY LTD (New PBS listing) PBS Section 100 (Highly Specialised Drugs Program)	Uncontrolled severe asthma Uncontrolled severe allergic asthma Severe chronic spontaneous urticaria	To request listing of two new forms of the Omlyclo biosimilar brand of omalizumab that mirror the originator brand's current listings with the same strengths and forms. Authority Required

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PEGCETACOPLAN Solution for subcutaneous infusion 1,080 mg in 20 mL Empaveli® SWEDISH ORPHAN BIOVITRUM PTY LTD (Change to existing listing) PBS Section 100 (Highly Specialised Drugs Program)	Complement 3 glomerulopathy (C3G) or primary immune complex membranoproliferative glomerulonephritis (IC-MPGN)	To request listing of pegcetacoplan for the treatment of patients aged 12 years and older with C3G or primary IC-MPGN. Authority Required (Written)
PEGVALIASE Injection 2.5 mg in 0.5 mL pre-filled syringe Injection 10 mg in 0.5 mL pre-filled syringe Injection 20 mg in 1 mL pre-filled syringe Palynziq® BIOMARIN PHARMACEUTICAL AUSTRALIA PTY LTD (New PBS listing) PBS General Schedule	Phenylketonuria (PKU)	Resubmission to request listing of pegvaliase for the treatment of patients aged 16 years and older with PKU who have inadequate blood phenylalanine control (baseline blood phenylalanine level above 600 micromoles per L) despite prior management with available treatment options (including a phenylalanine restricted diet and sapropterin). An inadequate response to a trial of sapropterin is defined as failure to achieve a 30 per cent or greater reduction in blood phenylalanine from baseline following initial treatment with sapropterin. The submission also seeks PBAC consideration for extending eligibility to patients aged 16 years and older with PKU who have a protein tolerance of less than 15 grams per day, even if sapropterin responsive. Authority Required (Telephone/Online)

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RESPIRATORY SYNCYTIAL VIRUS VACCINE Powder and suspension for injection (0.5 mL) Arexvy® GLAXOSMITHKLINE AUSTRALIA PTY LT (Change to existing NIP listing)	Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)	Resubmission to request a change to the National Immunisation Program (NIP) listing of Arexvy to extend eligibility to individuals aged 60 to 74 years who are at high risk of lower respiratory tract disease caused by RSV. The resubmission also requests that the PBAC reconsider the parameters upon which the cost-effectiveness of Arexvy was previously recommended for adults 75 years of age and above, and for Aboriginal and Torres Strait Islander peoples aged 60 to 74 years, based on updated clinical and epidemiological evidence.
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)	Merkel cell carcinoma (MCC)	To request listing of retifanlimab for the treatment of metastatic or recurrent, locally advanced MCC not amenable to curative surgery or radiation. This item was deferred at the November 2025 PBAC meeting. Authority Required (STREAMLINED)

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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)	Squamous cell anal carcinoma (SCAC)	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. This item was deferred at the November 2025 PBAC meeting. Authority Required (STREAMLINED)
RILUZOLE Oral suspension 50 mg per 10 mL, 300 mL Teglutik® ASTERI PHARMA PTY LTD (Change to existing listing) PBS General Schedule	Amyotrophic lateral sclerosis	To request that riluzole oral liquid 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 (Telephone/Online)

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RISPERIDONE Subcutaneous injection (modified release) 50 mg in 0.14 mL pre-filled syringe Subcutaneous injection (modified release) 75 mg in 0.21 mL pre-filled syringe Subcutaneous injection (modified release) 100 mg in 0.28 mL pre-filled syringe Subcutaneous injection (modified release) 125 mg in 0.35 mL pre-filled syringe Uzedy® TEVA PHARMA AUSTRALIA PTY LTD (New PBS listing) PBS General Schedule	Schizophrenia	To request listing of a new subcutaneous form of risperidone with multiple strengths for the treatment of adult patients with schizophrenia. Authority Required (STREAMLINED)
ROMIDEPSIN Injection set including 1 vial powder for injection 10 mg and 2 mL solvent Romidepsin-Reach REACH PHARMACEUTICALS PTY LTD (New PBS listing) PBS Section 100 (Efficient Funding of Chemotherapy Program)	Relapsed or refractory peripheral T-cell lymphoma	To request listing of romidepsin for the treatment of adult patients with peripheral T-cell lymphoma who have received at least one prior systemic therapy. Authority Required (Telephone/Online)

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RUXOLITINIB Tablet 5 mg Tablet 10 mg Tablet 15 mg Tablet 20 mg Jakavi® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED (Change to existing listing) PBS General Schedule	Myelofibrosis Graft versus host disease Polycythemia vera	To request a change to all existing listings of ruxolitinib for all indications to allow prescribing by nurse practitioners. Authority Required
SARS-CoV-2 mRNA Injection (0.5mL) Spikevax® MODERNA AUSTRALIA PTY LTD (New NIP listing)	Prevention of coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2	To request a National Immunisation Program (NIP) listing for the prevention of coronavirus disease 2019 (COVID-19) in individuals aged 18 years and older who have specific medical conditions that increase their risk of severe COVID-19.

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SELPERCATINIB Capsule 40 mg Capsule 80 mg Retevmo® ELI LILLY AUSTRALIA PTY LTD (Change to existing listing) PBS General Schedule	Medullary thyroid cancer (MTC)	To request listing of selpercatinib for the treatment of patients with advanced or metastatic MTC with a rearranged during transfection (RET) mutation. Authority Required (STREAMLINED)
TACROLIMUS Ointment 1 mg per g, 30 g aZematop® ARROTEX PHARMACEUTICALS PTY LTD (New PBS listing) PBS General Schedule	Atopic dermatitis	To request the PBAC review the revised proposed price, the restrictions, and the previously estimated utilisation of tacrolimus for the treatment of moderate to severe atopic dermatitis. This item was previously recommended by the PBAC at its July 2025 meeting.

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TAFAMIDIS Capsule 61 mg Vyndamax® PFIZER AUSTRALIA PTY LTD (Other matters) 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). Authority Required (Written or Telephone/Online) for initial treatment Authority Required (Telephone/Online) for continuing treatment
TAFASITAMAB Powder for I.V. infusion 200 mg Minjuvi® SPECIALISED THERAPEUTICS ALIM PTY LTD (New PBS listing) PBS Section 100 (Efficient Funding of Chemotherapy Program)	Relapsed and/or refractory follicular lymphoma (FL)	To request listing of tafasitamab for use in combination with lenalidomide and rituximab for the treatment of patients with relapsed and/or refractory FL. This item was deferred at the November 2025 PBAC meeting. Authority Required (Telephone/Online)

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TARLATAMAB Powder for injection 1 mg Powder for injection 10 mg Imdelltra® AMGEN AUSTRALIA PTY LIMITED (New PBS listing) PBS Section 100 (Efficient Funding of Chemotherapy Program)	Extensive-stage small cell lung cancer (ES-SCLC)	To request listing of tarlatamab for second-line and subsequent treatment of adult patients with ES-SCLC whose disease has progressed on or after platinum-based chemotherapy. Authority Required (STREAMLINED)
TECLISTAMAB Solution for subcutaneous injection 30 mg in 3 mL Solution for subcutaneous injection 153 mg in 1.7 mL Tecvayli® JANSSEN-CILAG PTY LTD (New PBS listing) PBS General Schedule PBS Section 100 (Efficient Funding of Chemotherapy Program)	Relapsed or refractory multiple myeloma (RRMM)	To request listing of teclistamab for the treatment of adult patients with RRMM who have received at least three prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody. Authority Required (Telephone/Online)

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TILDRAKIZUMAB Injection 100 mg in 1 mL single dose pre-filled syringe Ilumya® SUN PHARMA ANZ PTY LTD (Change to existing listing) PBS General Schedule	Severe chronic plaque psoriasis	To request a change to the existing listings for tildrakizumab for the continuing treatment of severe chronic plaque psoriasis, to allow the maintenance dose to be increased from 100 mg to 200 mg per administration, administered every 12 weeks. Authority Required

TIRZEPATIDE Solution for injection 2.5 mg in 0.5 mL vial/pre-filled pen Solution for injection 5 mg in 0.5 mL vial/pre filled pen Solution for injection 7.5 mg in 0.5 mL vial/pre-filled pen Solution for injection 10 mg in 0.5 mL vial/pre-filled pen Solution for injection 12.5 mg in 0.5 mL vial/pre-filled pen Solution for injection 15 mg in 0.5 mL vial/pre-filled pen Mounjaro® Injection 4.17 milligrams per mL (2.5 mg per dose) in multi-dose pre-filled pen, 4 dose Injection 8.33 milligrams per mL (5 mg per dose) in multi-dose pre-filled pen, 4 doses Injection 12.5 milligrams per mL (7.5 mg per dose) in multi-dose pre-filled pen, 4 doses Injection 16.67 milligrams per mL (10 mg per dose) in multi-dose pre-filled pen, 4 doses Injection 20.83 milligrams per mL (12.5 mg per dose) in multi-dose pre-filled pen, 4 doses Injection 25 milligrams per mL (15 mg per dose) in multi-dose pre-filled pen, 4 doses Mounjaro® KwikPen® ELI LILLY AUSTRALIA PTY LTD (New PBS listing) PBS General Schedule	Type 2 diabetes mellitus (T2DM)	Resubmission to request listing of tirzepatide for the treatment of adults with inadequately controlled T2DM. This item was deferred at the July 2025 PBAC meeting. Authority Required (Telephone/Online)

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TOCILIZUMAB Injection 162 mg in 0.9 mL single use pre-filled syringe Injection 162 mg in 0.9 mL single use pre-filled pen Actemra® Subcutaneous Injection Actemra® ACTPen ROCHE PRODUCTS PTY LTD (Change to existing listing) PBS General Schedule TO BE CONSIDERED AT A FUTURE PBAC MEETING	Active giant cell arteritis	To request the PBAC consider a change to the current listings of tocilizumab to remove the requirement for elevated erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) levels in patients with biopsy-proven giant cell arteritis.
TOFERSEN Solution for intrathecal injection 100 mg in 15 mL Qalsody® BIOGEN AUSTRALIA PTY LTD (New PBS listing) PBS Section 100 (Highly Specialised Drugs Program)	Amyotrophic lateral sclerosis (ALS)	Resubmission 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. Authority Required (Telephone/Online)

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TRASTUZUMAB DERUXTECAN Powder for I.V. infusion 100 mg Enhertu® ASTRAZENECA PTY LTD (Change to existing listing) PBS Section 100 (Efficient Funding of Chemotherapy Program)	Breast cancer	To request listing of trastuzumab deruxtecan for the treatment of adult patients with hormone receptor positive (HR-positive) human epidermal growth factor receptor 2 (HER2)-low or HER2-ultralow unresectable and/or metastatic breast cancer who have received at least one prior line of endocrine therapy in the metastatic setting and are no longer suitable for further endocrine therapy. Authority Required (Telephone/Online)
UPADACITINIB Tablet 15 mg Tablet 30 mg Tablet 45 mg Rinvoq® ABBVIE PTY LTD (Change to existing listing) PBS General Schedule)	Fistulising Crohn's disease (FCD)	To request listing of upadacitinib for the treatment of adult patients with complex refractory FCD who have an externally draining enterocutaneous or rectovaginal fistula. Authority Required (Written) for initial treatment Authority Required (Telephone/Online) for continuing treatment

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USTEKINUMAB Injection 45 mg in 0.5 mL single use pre-filled syringe Injection 90 mg in 1 mL single use pre-filled syringe Ardelya® SANDOZ PTY LTD (New PBS listing) PBS General Schedule	Severe chronic plaque psoriasis Severe psoriatic arthritis	To request listing of a new ustekinumab biosimilar for the treatment of severe chronic plaque psoriasis and severe psoriatic arthritis that mirrors the originator brand's current listings. Authority Required
VORASIDENIB Tablet 10 mg Tablet 40 mg Voranigo® SERVIER LABORATORIES (AUST.) PTY. LTD. (New PBS listing) PBS General Schedule	Astrocytoma or oligodendroglioma	Resubmission to request listing of vorasidenib for the treatment of adult patients with isocitrate dehydrogenase-mutant astrocytoma or oligodendroglioma who have residual or recurrent disease after at least one prior surgery. Authority Required (STREAMLINED)

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FLUTICASONE PROPIONATE 50 microgram/actuation inhalation, 120 actuations All brands Various sponsors (DUSC analysis)	Asthma in patients aged 6 years and over	To assess the utilisation of PBS listed 50 microgram/actuation fluticasone propionate in patients aged 6 years and over.
MEPOLIZUMAB 100 mg/mL injection, 1 mL pen device Nucala® GLAXOSMITHKLINE AUSTRALIA PTY LTD (DUSC analysis)	Chronic rhinosinusitis with nasal polyps	To assess the utilisation of PBS listed mepolizumab for chronic rhinosinusitis.
CABOZANTINIB Tablet 20 mg Tablet 40 mg Cabometyx® IPSEN PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Clear cell variant renal cell carcinoma	To request the PBAC review its March 2024 recommendation that has not yet been accepted by the applicant.

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HUMAN MENOPAUSAL GONADOTROPHIN Injection 600 I.U. in 0.96 mL pre-filled multi-dose pen Injection 1200 I.U. in 1.92 mL pre-filled multi-dose pen Menopur® 600 Menopur® 1200 FERRING PHARMACEUTICALS PTY LIMITED (Review of positive PBAC recommendations not accepted by applicants)	In Vitro fertilisation	To request the PBAC review its July 2022 recommendation that has not yet been accepted by the applicant.
INFLUENZA VACCINE Injection 0.5 mL Flublok® Quadrivalent SANOFI-AVENTIS AUSTRALIA PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Prevention of influenza	To request the PBAC review its March 2024 recommendation that has not yet been accepted by the applicant.

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LEBRIKIZUMAB Injection 250 mg in 2 mL single use autoinjector Ebglyss® ELI LILLY AUSTRALIA PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Atopic dermatitis	To request the PBAC review its March 2024 recommendation that has not yet been accepted by the applicant.
MULTICOMPONENT MENINGOCOCCAL GROUP B VACCINE Injection (0.5mL) Bexsero® GLAXOSMITHKLINE AUSTRALIA PTY LTD (Change to existing NIP listing)	Prevention of invasive meningococcal disease (IMD) caused by *Neisseria meningitidis* group B strains	To consider a proposal to expand the current National Immunisation Program (NIP) listing of Bexsero® for use in broader infant and adolescent populations.

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PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® MERCK SHARP & DOHME (Australia) PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Gastroesophageal cancers	To request the PBAC review its May 2022 recommendation that has not yet been accepted by the applicant.
PNEUMOCOCCAL CONJUGATE VACCINE, 15-VALENT ADSORBED 0.5 mL pre-filled syringe Vaxneuvance® MERCK SHARP & DOHME (Australia) PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Prevention of pneumococcal disease	To request the PBAC review its March 2023 recommendation that has not yet been accepted by the applicant.

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PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE, 15-VALENT ADSORBED 0.5 mL pre-filled syringe Trade name: To be determined MERCK SHARP & DOHME (Australia) PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Prevention of pneumococcal disease	To request the PBAC review its November 2021 recommendation that has not yet been accepted by the applicant.
PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE, 20-VALENT ADSORBED 0.5 mL pre-filled syringe Prevenar 20® PFIZER AUSTRALIA PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Prevention of pneumococcal disease	To request the PBAC review its November 2022 recommendation that has not yet been accepted by the applicant.

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SODIUM ZIRCONIUM CYCLOSILICATE Sachet containing powder for oral suspension (as hydrate) 5 g Sachet containing powder for oral suspension (as hydrate) 10 g Lokelma® ASTRAZENECA PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Hyperkalaemia in patients with chronic kidney disease	To request the PBAC review its March 2024 recommendation that has not yet been accepted by the applicant.
TOFACITINIB Tablet (modified release) 11 mg Xeljanz® XR PFIZER AUSTRALIA PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Rheumatoid arthritis Psoriatic arthritis	To request the PBAC review its March 2024 recommendation that has not yet been accepted by the applicant.

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TRIENTINE Tablet 150 mg (as tetrahydrochloride) Cuprior® ORPHALAN (Review of positive PBAC recommendations not accepted by applicants)	Wilson disease	To request the PBAC review its May 2022 recommendation that has not yet been accepted by the applicant.
USTEKINUMAB Injection 45 mg in 0.5 mL single use pre-filled syringe Injection 45 mg in 0.5 mL single use pre-filled pen Injection 90 mg in 1 mL single use pre-filled syringe Injection 90 mg in 1 mL single use pre-filled pen Stelara® JANSSEN-CILAG PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Psoriatic arthritis Chronic plaque psoriasis Crohn disease Ulcerative colitis Complex refractory fistulising Crohn disease	To request the PBAC review its March 2024 recommendation that has not yet been accepted by the applicant.

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USTEKINUMAB Injection 45 mg in 0.5 mL Injection 45 mg in 0.5 mL single use pre-filled syringe Injection 90 mg in 1 mL single use pre-filled syringe Solution for I.V. infusion 130 mg in 26 mL Wezlana® AMGEN AUSTRALIA PTY LIMITED (Review of positive PBAC recommendations not accepted by applicants)	Psoriatic arthritis Chronic plaque psoriasis Crohn disease Ulcerative colitis Complex refractory fistulising Crohn disease	To request the PBAC review its March 2024 recommendation that has not yet been accepted by the applicant.
Review of designated Registered Nurse prescribing Various forms and strengths Various brands Various sponsors (Other matters)	Various	To request the PBAC's review of the suitability of medicines within the listings presented for designated Registered Nurse prescribing.

Version 7
Items added or amended
1. ALECTINIB (Alecensa®) – Purpose of submission amended

Items added or amended previously
2. ADALIMUMAB (various brands) and INFLIXIMAB (various brands) – Added

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3. ALECTINIB (Alecensa®) – Added
4. ASCIMINIB (Scemblix®) – Purpose of submission amended
5. ASCIMINIB (Scemblix®) – Withdrawn
6. BIRCH TRITERPENES (Filsuvez®) – To be considered at a future PBAC meeting
7. CABOZANTINIB (Cabometyx®) – Review of positive PBAC recommendations not accepted by applicants – Added
8. DUPILUMAB (Dupixent®) – Purpose of submission amended
9. EDARAVONE (Radicava®) – To be considered prior to the March 2026 meeting, and consumer consultation will close on 9 January 2026
10. ENOXAPARIN (Clexane® Safety-Lock and Clexane® Forte Safety-Lock) – Withdrawn
11. HUMAN MENOPAUSAL GONADOTROPHIN (Menopur® 600, Menopur® 1200) – Review of positive PBAC recommendations not accepted by applicants – Added
12. INFLUENZA VACCINE (Flublok® Quadrivalent) – Review of positive PBAC recommendations not accepted by applicants – Added
13. LEBRIKIZUMAB (Ebglyss®) – Review of positive PBAC recommendations not accepted by applicants – Added
14. MULTICOMPONENT MENINGOCOCCAL GROUP B VACCINE (Bexsero®) – Added
15. NIVOLUMAB (Opdivo®) – Purpose of submission amended
16. OBINUTUZUMAB (Gazyva®) – Brand name amended
17. PEMBROLIZUMAB (Keytruda®) – Review of positive PBAC recommendations not accepted by applicants – Added
18. PNEUMOCOCCAL CONJUGATE VACCINE, 15-VALENT ADSORBED (Vaxneuvance®) – Review of positive PBAC recommendations not accepted by applicants – Added
19. PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE, 15-VALENT ADSORBED (TBD) – Review of positive PBAC recommendations not accepted by applicants – Added
20. PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE, 20-VALENT ADSORBED (Prevenar 20®) – Review of positive PBAC recommendations not accepted by applicants – Added
21. RETIFANLIMAB (Zynyz®) – MCC – Added
22. RETIFANLIMAB (Zynyz®) – SCAC – Added
23. Review of designated Registered Nurse prescribing (Various brands) – Added
24. SODIUM ZIRCONIUM CYCLOSILICATE (Lokelma®) – Review of positive PBAC recommendations not accepted by applicants – Added
25. TACROLIMUS (aZematop®) – Added
26. TAFASITAMAB (Minjuvi®) – Added
27. TIRZEPATIDE (Mounjaro®, Mounjaro® KwikPen®) – Added
28. TOCILIZUMAB (Actemra® Subcutaneous Injection, Actemra® ACTPen) – Added
29. TOCILIZUMAB (Actemra® Subcutaneous Injection, Actemra® ACTPen) – To be considered at a future PBAC meeting
30. TOFACITINIB (Xeljanz® XR) – Review of positive PBAC recommendations not accepted by applicants – Added
31. TOFERSEN (Qalsody®) – Added
32. TRIENTINE (Cuprior®) – Review of positive PBAC recommendations not accepted by applicants – Added
33. USTEKINUMAB (Stelara®) – Review of positive PBAC recommendations not accepted by applicants – Added
34. USTEKINUMAB (Wezlana®) – Review of positive PBAC recommendations not accepted by applicants – Added
35. VORASIDENIB (Voranigo®) – Added