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

Closing date for consumer consultation 20 May 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.

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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.

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.)
ACALABRUTINIB Tablet 100 mg Calquence® ASTRAZENECA PTY LTD Change to existing listing PBS General Schedule	Mantle cell lymphoma (MCL)	To consider the sponsor's revised proposal for listing acalabrutinib for use in combination with bendamustine and rituximab for the first-line treatment of adult patients with Stage III or IV MCL who are ineligible for stem cell transplantation. This item was previously recommended by the PBAC at its July 2025 meeting. Authority Required (Telephone/Online)

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AMIVANTAMAB Solution for subcutaneous injection 1600 mg in 10 mL Solution for subcutaneous injection 2240 mg in 14 mL Solution for subcutaneous injection 2400 mg in 15 mL Solution for subcutaneous injection 3520 mg in 22 mL Rybrevant SC® JANSSEN-CILAG PTY LTD New PBS listing PBS General Schedule PBS Section 100 (Efficient Funding of Chemotherapy)	Non-small cell lung cancer (NSCLC)	To request listing of a new subcutaneous form of amivantamab for the first-line treatment (in combination with platinum-based chemotherapy) and second-line treatment (as monotherapy) of adult patients with locally advanced or metastatic NSCLC with an epidermal growth factor receptor gene mutation. Authority Required (Telephone/Online)

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APADAMTASE ALFA WITH CINAXADAMTASE ALFA (recombinant ADAMTS13) Powder for injection 500 I.U. with solvent Powder for injection 1500 I.U. with solvent Adzynma® TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD. New PBS listing PBS Section 100 (Highly Specialised Drugs Program)	Congenital thrombotic thrombocytopenic purpura (cTTP)	To request listing of apadamtase alfa with cinaxadamtase alfa (an enzyme replacement therapy) for the prevention of acute events in adult and paediatric patients with chronic, severe cTTP who have a confirmed ADAMTS13 genetic mutation and ADAMTS13 activity levels less than 10% and who cannot tolerate, or are hypersensitive to, preventative treatment with fresh frozen plasma. Authority Required (Telephone/Online)
BELANTAMAB MAFODOTIN Powder for injection 70 mg (50 mg per ml) Powder for injection 100 mg (50 mg per ml) Blenrep® GLAXOSMITHKLINE AUSTRALIA PTY LTD New PBS listing PBS Section 100 (Efficient funding of Chemotherapy)	Relapsed and/or refractory multiple myeloma (MM)	Resubmission to request listing of belantamab mafodotin for use in combination with bortezomib and dexamethasone for the treatment of relapsed and/or refractory MM in patients who have progressive disease after at least one prior line of therapy. This item was previously considered by the PBAC at its November 2025 meeting. Authority Required (Telephone/Online)

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BEMPEDOIC ACID Tablet 180mg Nexletol® BEMPEDOIC ACID WITH EZETIMIBE Tablet 180mg bempedoic acid with 10 mg ezetimibe Nexlizet® SEQIRUS (AUSTRALIA) PTY LTD New PBS listing PBS General Schedule	Hypercholesterolaemia	To request listing of bempedoic acid, as monotherapy and in combination with ezetimibe, for the treatment of adult patients with hypercholesterolaemia (heterozygous familial and non-familial) at high risk of a first cardiovascular event or with established symptomatic atherosclerotic cardiovascular disease who have statin intolerance or are on maximally tolerated statin therapy, and despite treatment with ezetimibe, continue to have low-density lipoprotein cholesterol (LDL-C) levels greater than 1.8 mmol/L. Authority Required (STREAMLINED)
BIRCH TRITERPENES Gel containing 100 mg per 1 g, 23.4 g Filsuvez® CHIESI AUSTRALIA PTY LTD (New PBS Listing) PBS General Schedule	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.

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BRENTUXIMAB VEDOTIN Powder for I.V. infusion 50 mg Adcetris® TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD. Change to existing listing PBS Section 100 (Efficient Funding of Chemotherapy)	Hodgkin lymphoma	To request listing of brentuximab vedotin for use in combination with a multi-drug chemotherapy regimen for the first-line treatment of adult patients with advanced stage CD30 positive Hodgkin lymphoma. Authority Required (Written)
BUDESONIDE WITH GLYCOPYRRONIUM AND FORMOTEROL Pressurised inhalation containing budesonide 160 micrograms with glycopyrronium 14.4 micrograms and formoterol fumarate dihydrate 5 micrograms per dose, 120 doses Breztri Aerosphere® ASTRAZENECA PTY LTD New PBS listing PBS General Schedule TO BE CONSIDERED AT A FUTURE PBAC MEETING	Severe asthma	To request listing of a new form of budesonide with glycopyrronium and formoterol for the maintenance treatment of severe asthma in adult patients not adequately controlled with a maintenance combination of a long acting beta agonist (LABA) and an inhaled corticosteroid (ICS) who experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma. Authority Required (STREAMLINED)

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DEPEMOKIMAB Solution for subcutaneous injection 100 mg in 1 mL Exdensur® GLAXOSMITHKLINE AUSTRALIA PTY LTD New PBS listing PBS Section 100 (Highly Specialised Drugs Program)	Uncontrolled severe eosinophilic asthma	To request listing of depemokimab for the treatment of uncontrolled severe eosinophilic asthma in patients aged 12 years or older with a blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months, or with a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months. Authority Required (Written) for initial treatment Authority Required (STREAMLINED) for continuing treatment
DONIDALORSEN Solution for injection 80 mg in 0.8 mL pre-filled pen Zirdawny® OTSUKA AUSTRALIA PHARMACEUTICAL PTY. LTD New PBS listing PBS General Schedule	Hereditary angioedema	To request listing of donidalorsen for the long-term prophylaxis (prevention) of recurrent attacks in patients with hereditary angioedema. Authority Required (Written)

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ELACESTRANT Tablet 86 mg (as dihydrochloride) Tablet 345 mg (as dihydrochloride) Orserdu® A.MENARINI AUSTRALIA PTY LIMITED New PBS listing PBS General Schedule	Breast cancer	Resubmission to request listing of elacestrant for the treatment of estrogen receptor-positive, human epidermal growth factor receptor 2-negative (ER+/HER2-) locally advanced or metastatic breast cancer with an activating estrogen receptor 1 mutation in patients who have disease progression following at least one line of endocrine therapy, including at least 12 months of treatment with a cyclin-dependent kinase 4/6 inhibitor. This item was previously considered by the PBAC at its March 2025 meeting. Authority Required (Telephone/Online)
FINERENONE Tablet 10 mg Tablet 20 mg Tablet 40 mg Kerendia® BAYER AUSTRALIA LTD New PBS listing PBS General Schedule	Heart failure	To request listing of finerenone for the treatment of adult patients with symptomatic heart failure (New York Heart Association (NYHA) Class II-IV) and a left ventricular ejection fraction (LVEF) of greater than or equal to 40%. Authority Required (STREAMLINED)

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GUSELKUMAB Solution for I.V. infusion 200 mg in 20 mL vial Injection 100 mg in 1 mL single use pre-filled pen Injection 200 mg in 2 mL single use pre-filled pen Injection 100 mg in 1 mL single use pre-filled syringe Injection 200 mg in 2 mL single use pre-filled syringe Tremfya® JANSSEN-CILAG PTY LTD New PBS listing PBS General Schedule PBS Section 100 (Highly Specialised Drugs Program)	Severe Crohn disease (CD)	To consider the sponsor's revised proposal for listing guselkumab for the treatment of adult patients with severe CD who have failed to achieve an adequate response to prior systemic therapy (i.e. corticosteroids and at least 3 months of immunosuppressive therapy). This item was previously recommended by the PBAC at its July 2025 meeting. Authority Required (Written)

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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)	Resubmission 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
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	Termination of an intra-uterine pregnancy	To request a change to the existing listing of mifepristone and misoprostol for the termination of an intra-uterine pregnancy, such that the condition must be an intra-uterine pregnancy of up to 70 days of gestation (compared to 63 days of gestation with the existing listing). Authority Required (STREAMLINED)

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ONASEMNOGENE ABEPARVOVEC 1 vial solution for intrathecal injection 1.2 x 1014 vector genomes per mL, 3 mL OAV101 IT® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED New PBS listing PBS Section 100 (Highly Specialised Drugs Program)	Spinal muscular atrophy (SMA)	To request listing of intrathecal onasemnogene abeparvovec for the treatment of symptomatic SMA in patients at least 2 years of age but yet to turn 19 years old who have experienced at least two of the defined signs and symptoms of SMA Type I, II or IIIa prior to 3 years of age. Authority Required (Written)
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)	Resubmission to request listing of odevixibat for the treatment of cholestatic pruritis in ALGS in patients aged 6 months and older. 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)	Resubmission 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. This item was deferred at the March 2026 PBAC meeting. Authority Required (Telephone/Online)

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PEGZILARGINASE Solution for injection 2 mg in 0.4 mL Loargys® ILLUMINATE HEALTH CONSULTING PTY LIMITED New PBS listing PBS Section 100 (Highly Specialised Drugs Program)	Arginase 1 deficiency (ARG1-D)	To request listing of pegzilarginase for the treatment of ARG1-D (also known as hyperargininaemia) in patients aged 2 years or older. Authority Required (Written) for initial treatment Authority Required (Telephone/Online) for continuing treatment
PIRTOBRUTINIB Tablet 50mg Tablet 100mg Jaypirca® ELI LILLY AUSTRALIA PTY LTD New PBS listing PBS General Schedule	Chronic lymphocytic leukaemia (CLL) Small lymphocytic lymphoma (SLL)	To request listing of pirtobrutinib for the treatment of adult patients with relapsed or refractory CLL/SLL who have received at least one prior therapy (as second or subsequent-line treatment) and require treatment according to the International Workshop on CLL (iwCLL). Authority Required (Telephone/Online)

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PROGESTERONE Pessary 400 mg Utrogestan® BESINS HEALTHCARE AUSTRALIA PTY LTD New PBS listing PBS General Schedule	Unexplained threatened miscarriage	To request listing of progesterone for the treatment of unexplained threatened miscarriage in the first trimester, with vaginal bleeding in the current pregnancy and a history of previous miscarriage. Authority Required (STREAMLINED)
SEBELIPASE ALFA Solution for injection 20 mg in 10 mL vial Kanuma® ALEXION PHARMACEUTICALS PTY LIMITED New PBS listing PBS Section 100 (Highly Specialised Drugs Program)	Late-onset lysosomal acid lipase deficiency (LAL-D)	To request listing of sebelipase alfa (as a long-term enzyme replacement therapy) for the treatment of children and adults with late-onset LAL-D who are receiving, or enrolled to receive, professional nutritional support including dietetic and weight management advice. Authority Required (Written)

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TEPLIZUMAB Solution for injection 2 mg in 2 mL Tzield® SANOFI-AVENTIS AUSTRALIA PTY LTD New PBS listing PBS Section 100 (Highly Specialised Drugs Program)	Type 1 diabetes (T1D)	To request listing of teplizumab for the treatment of Stage 2 T1D in patients aged 8 years or older in order to delay the onset of Stage 3 T1D. Authority Required
TISLELIZUMAB Solution concentrate for I.V. infusion 100 mg in 10 ml Solution concentrate for I.V. infusion 150 mg in 15 ml Tevimbra® BEONE MEDICINES AUS PTY LTD New PBS listing PBS Section 100 (Efficient Funding of Chemotherapy)	Gastro-oesophageal cancer	To request listing of tislelizumab for advanced or metastatic gastro-oesophageal cancer such that patients can be administered treatment with 150 mg once every two weeks (Q2W) and 300 mg once every four weeks (Q4W) as an alternative to the current dosing regimen of 200 mg once every 3 weeks (Q3W). The submission also seeks listing of a new 150 mg vial form of tislelizumab. Authority Required (STREAMLINED)

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VUTRISIRAN Injection 25 mg (as sodium) in 0.5 mL pre-filled syringe Amvuttra® MEDISON PHARMA AUSTRALIA PTY LIMITED Change to existing listing PBS General Schedule	Transthyretin amyloid cardiomyopathy (ATTR-CM)	To request listing of vutrisiran for the treatment of adult patients with wild-type or hereditary ATTR-CM with documented evidence of the transthyretin precursor protein present who have experienced at least one episode of hospitalisation that was a direct result of heart failure or have clinical evidence of heart failure without hospitalisation that required treatment with a diuretic for improvement. Authority Required (Written) for initial treatment Authority Required (Telephone/Online) for continuing treatment

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Other items

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Life Saving Drugs Program (LSDP) medicines for Fabry disease AGALSIDASE ALFA Solution for I.V. injection 3.5 mg in 3.5 mL vial Replagal® TAKEDA PHARMACEUTICALS AUSTRALIA PTY LIMITED AGALSIDASE BETA Powder for I.V. infusion, 5 mg vial Powder for I.V. infusion, 35 mg vial Fabrazyme® SANOFI AUSTRALIA AND NEW ZEALAND New PBS listing	Fabry disease	Referral from the Life Saving Drugs Panel (LSDP) Expert Panel seeking the PBAC's advice on whether agalsidase alfa and agalsidase beta are suitable for PBS listing for the treatment of Fabry disease under the same conditions as the PBAC's recommendations for the PBS listing of pegunigalsidase alfa at its July 2025 meeting.

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Atomoxetine and guanfacine All forms and strengths Various brands (Other matters) TO BE CONSIDERED AT A FUTURE PBAC MEETING	Attention deficit hyperactivity disorder (ADHD)	Tranche 1 of Post Market Review (PMR) work plan - Attention Deficit Hyperactivity Disorder (ADHD) research project. To consider the cost estimates and changes in drug utilisation for amending the Pharmaceutical Benefits Scheme (PBS) restrictions for atomoxetine and guanfacine for ADHD.
Azithromycin for the treatment of diphtheria Tablet 500 mg (as dihydrate) Powder for oral suspension 200 mg (as dihydrate) per 5 mL, 15 mL Various brands Various sponsors (Other matters)	Diphtheria	To request advice on options for expanding the PBS subsidy arrangements of azithromycin in response to the diphtheria outbreak in the Northern Territory and Western Australia.
High clinical unmet need and high added therapeutic value project update (Other matters)	Not applicable	To note an update regarding the research project into areas of high unmet clinical need (HUCN) and high added therapeutic value (HATV), including agreed definitions for these terms.

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PBAC Guidelines and Streamlined Assessment Project Update (Other matters)	Not applicable	To note an update regarding the amendments to the PBAC Guidelines for discount rate and comparator selection, and the development of new streamlined pathways for cost-minimisation submissions and co-dependent submissions.
Prescribing conditions for 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 Various brands Various sponsors (Other matters)	Acromegaly Functional carcinoid tumour Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)	The PBAC is requested to advise whether initial treatment and prescribing of lanreotide should remain restricted to hospital associated medical practitioners and specialists.
Review of designated Registered Nurse prescribing (Other matters)	Various	To review and provide advice on the department's recommendations for assessed medicines for designated registered nurse (RN) prescribing.

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ANTIVIRALS FOR THE TREATMENT OF SEVERE-ACUTE-RESPIRATORY SYNDROME CORONAVIRUS-2 (SARS-COV-2) INFECTION All brands and strengths Various sponsors (Sub-committee report DUSC analysis)	SARS-CoV-2 infection	To assess the utilisation of PBS listed antivirals for the treatment of SARS-CoV-2 infection.
ENFORTUMAB VEDOTIN 20 mg injection, 1 vial 30 mg injection, 1 vial Padcev® Astellas Pharma Australia Pty Ltd (Sub-committee report DUSC analysis)	Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer	To assess the utilisation of PBS listed enfortumab vedotin for stage III or stage IV urothelial cancer.
PEMBROLIZUMAB 100 mg/4 mL injection, 4 mL vial Keytruda® Merck Sharp & Dohme (Australia) Pty Ltd (Sub-committee report DUSC analysis)	Stage II or stage III and recurrent, unresectable or metastatic triple negative breast cancer.	To assess the utilisation of PBS listed pembrolizumab for stage II or stage III and recurrent, unresectable or metastatic triple negative breast cancer.

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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.)
APALUTAMIDE Tablet 240 mg Erlyand® JANSSEN-CILAG PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Prostate cancer	To request the PBAC review its July 2024 recommendation that has not yet been accepted by the applicant.
LEVODOPA WITH CARBIDOPA AND ENTACAPONE Intestinal gel containing levodopa 20 mg with carbidopa monohydrate 5 mg and with entacapone 20 mg per mL, 47 mL Lecigon® STADA PHARMACEUTICALS AUSTRALIA PTY LIMITED (Review of positive PBAC recommendations not accepted by applicants)	Parkinson disease	To request the PBAC review its July 2024 recommendation that has not yet been accepted by the applicant.

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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.)
PROGESTERONE Capsule 300 mg Ultrogestan® BESINS HEALTHCARE AUSTRALIA PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	In vitro fertilisation	To request the PBAC review its July 2024 recommendation that has not yet been accepted by the applicant.

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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.)
AFLIBERCEPT Solution for intravitreal injection 3.6 mg in 90 microlitres (40 mg per mL) pre-filled syringe Solution for intravitreal injection 4 mg in 100 microlitres (40 mg per mL) Eydenzelt® CELLTRION HEALTHCARE AUSTRALIA PTY LTD New PBS listing PBS General Schedule	Branch retinal vein occlusion with macular oedema Central retinal vein occlusion with macular oedema Diabetic macular oedema Subfoveal choroidal neovascularisation due to age-related macular degeneration	To request listing of four new indications for the Eydenzelt brand of aflibercept that mirror the originator brand's current listings. Eydenzelt was originally recommended for listing as a biosimilar brand of aflibercept at the November 2025 PBAC meeting for the subfoveal choroidal neovascularisation due to pathologic myopia indication. Authority Required

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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.)
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN Oral powder 400 g (GA1 Anamix infant) Sachets containing oral powder 18 g, 30 (GA1 Anamix Junior) GA1 Anamix Infant® GA1 Anamix Junior® NUTRICIA AUSTRALIA PTY LTD Change to existing listing PBS General Schedule	Pyridoxine-Dependent Epilepsy (PDE)	To request listing of GA1 Anamix Infant and GA1 Anamix Junior for the dietary management of infants and children diagnosed with PDE who require a lysine-free, arginine-supplemented amino-acid formula in combination with pyridoxine. Restricted Benefit

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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.)
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE Oral powder 400 g (MSUD Anamix infant) Sachets containing oral powder 36 g, 30 (MSUD Anamix Junior) Oral liquid 125 mL, 30 (MSUD Lophlex LQ 20) Oral powder 500 g (MSUD Maxamum) MSUD Anamix Infant® MSUD Anamix Junior® MSUD Lophlex LQ 20® MSUD Maxamum® NUTRICIA AUSTRALIA PTY LTD Change to existing listing PBS General Schedule	Short-chain enoyl-CoA hydratase (ECHS1) deficiency	To request listing of MSUD Anamix Infant, MSUD Anamix Junior, MSUD Lophlex LQ 20 and MSUD Maxamum for the dietary management of infants and children with ECHS1 deficiency (the same dietary management approach used in Maple Syrup Urine Disease (MSUD)). Restricted Benefit

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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.)
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE Sachets containing oral powder 25 g, 30 (MSUD express 15) MSUD express 15® VITAFLO AUSTRALIA PTY LIMITED Change to existing listing PBS General Schedule	Short-chain Enoyl co-A Hydratase (ECHS1) deficiency and 3-Hydroxyisobutyryl co-A Hydrolase (HIBCH) deficiency	To request listing of MSUD express15 for the dietary management of patients aged 3 years and over with a proven diagnosis of either ECHS1 or HIBCH deficiency. Restricted Benefit
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE, ISOLEUCINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID Sachets containing oral powder 12.5 g, 30 (MSUD Explore5) MSUD explore5® VITAFLO AUSTRALIA PTY LIMITED Change to existing listing PBS General Schedule	Short-chain Enoyl co-A Hydratase (ECHS1) deficiency and 3-Hydroxyisobutyryl co-A Hydrolase (HIBCH) deficiency	To request listing of MSUD explore5 for the dietary management of patients aged 6 months to 5 years with a proven diagnosis of either ECHS1 or HIBCH deficiency. Restricted Benefit

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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.)
ANIFROLUMAB Solution for subcutaneous injection 120 mg in 0.8 mL Saphnelo® ASTRAZENECA PTY LTD New PBS listing PBS General Schedule	Systemic lupus erythematosus (SLE)	To request listing of a new subcutaneous form of anifrolumab for use as add-on treatment for adult patients with severe SLE with persistent disease activity (supported by a SLE Disease Activity Index 2000 score of at least 10 points) despite standard of care with hydroxychloroquine, immunosuppressant medication and prednisolone (or equivalent). Authority Required (Written)
ATEZOLIZUMAB Solution for subcutaneous injection 1875 mg in 15 mL Tecentriq SC® LICENSED STERILE COMPOUNDERS OF AUSTRALIA LIMITED New PBS listing PBS Section 100 (Efficient funding of Chemotherapy) WITHDRAWN	Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma Extensive-stage small cell lung cancer Resected early stage (Stage II to IIIA) non-small cell lung cancer Locally advanced or metastatic non-small cell lung cancer Stage IV (metastatic) non-small cell lung cancer	To request that the listings for the subcutaneous form of atezolizumab transition to the Section 100 (Efficient Funding of Chemotherapy) program. Authority Required

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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.)
AZACITIDINE Powder for injection 100 mg Azacitidine Accord® Azacitidine Dr Reddy's® Azacitidine Euglia® Azacitidine Juno® Azacitidine MSN® Azacitidine Sandoz® Azacitidine SXP® LICENSED STERILE COMPOUNDERS OF AUSTRALIA LIMITED New PBS listing PBS Section 100 (Efficient funding of Chemotherapy) TO BE CONSIDERED AT A FUTURE PBAC MEETING	Acute Myeloid Leukemia Myelodysplastic syndrome Chronic Myelomonocytic Leukemia	To request that the listings for azacitdine transition to the Section 100 (Efficient Funding of Chemotherapy) program. Authority Required

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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.)
BLINATUMOMAB Powder for I.V. infusion 38.5 micrograms Blincyto® AMGEN AUSTRALIA PTY LIMITED Change to existing listing PBS Section 100 (Efficient Funding of Chemotherapy)	Acute lymphoblastic leukaemia (ALL) Precursor B-cell ALL (Pre-B-cell ALL)	To request revision of the current combined blinatumomab/inotuzumab ozogamicin Risk Sharing Arrangement (RSA) for ALL and Pre-B-cell ALL. Authority Required
BRIVARACETAM Oral solution 10 mg per mL, 300 mL Briviact® UCB AUSTRALIA PROPRIETARY LIMITED Change to existing listing PBS General Schedule	Intractable focal onset seizures	To request that brivaracetam 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 (STREAMLINED)

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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.)
CLOZAPINE Tablet 12.5mg (orally disintegrating) Tablet 25mg (orally disintegrating) Tablet 50mg (orally disintegrating) Tablet 100mg (orally disintegrating) Tablet 200mg (orally disintegrating) Clozaril® VIATRIS PTY LTD New PBS listing PBS Section 100 (Highly Specialised Drugs Program)	Schizophrenia	To request listing of new orally disintegrating tablet forms of clozapine for the treatment of patients with schizophrenia under the same restrictions as the currently listed tablet forms. Authority Required (STREAMLINED)

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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.)
DARATUMUMAB Solution for subcutaneous injection containing daratumumab 1800 mg in 15 mL Darzalex SC® LICENSED STERILE COMPOUNDERS OF AUSTRALIA LIMITED New PBS listing PBS Section 100 (Efficient Funding of Chemotherapy) TO BE CONSIDERED AT A FUTURE PBAC MEETING	Newly diagnosed systemic light chain amyloidosis Untreated multiple myeloma Relapsed and/or refractory multiple myeloma	To request that the listings for the subcutaneous form of daratumumab transition to the Section 100 (Efficient Funding of Chemotherapy) program. Authority Required
DELGOCITINIB Cream 20 mg per g, 60 g Anzupgo® LEO PHARMA PTY LTD New PBS listing PBS General Schedule	Chronic hand eczema (CHE)	To consider the sponsor's revised proposal for listing delgocitinib for the treatment of moderate to severe CHE where topical corticosteroids failed to achieve an adequate response or are medically inappropriate. This item was previously recommended by the PBAC at its November 2025 meeting. Authority Required (Written)

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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.)
DUPILUMAB Injection 200 mg in 1.14 mL single dose pre-filled syringe Injection 200 mg in 1.14 mL single dose pre-filled pen 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 severe atopic dermatitis	To consider the sponsor's revised proposal for listing dupilumab for the treatment of chronic severe atopic dermatitis in children aged 6 months to 11 years who have had lesions for at least 6 months from the time of the initial diagnosis affecting either the whole body or the face/hands. This item was previously recommended by the PBAC at its March 2022 meeting. Authority Required (Telephone/Online)

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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.)
ELEXACAFTOR WITH TEZACAFTOR AND WITH IVACAFTOR, AND IVACAFTOR Pack containing 28 sachets containing granules elexacaftor 100 mg with tezacaftor 50 mg and with ivacaftor 75 mg and 28 sachets containing granules ivacaftor 75 mg Trikafta® VERTEX PHARMACEUTICALS (AUSTRALIA) PTY. LTD. Change to existing listing PBS Section 100 (Highly Specialised Drugs Program)	Cystic fibrosis	To request a change to the existing listing for Trikafta (granules formulation) for the treatment of cystic fibrosis to allow patients aged 6-11 years weighing less than 30 kg to use either the granule or tablet formulation of the same dose. Authority Required (Written)
ELTROMBOPAG Tablet 75 mg (as olamine) Revolade® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED New PBS listing PBS Section 100 (Highly Specialised Drugs Program)	Severe aplastic anaemia Severe thrombocytopenia	To request listing of a new 75 mg strength of eltrombopag for the treatment of patients with severe aplastic anaemia and severe thrombocytopenia under the same restrictions as the currently listed tablet forms. Authority Required (Written or Telephone/Online)

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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.)
EPCORITAMAB Solution concentrate for subcutaneous injection 4 mg in 0.8 mL Solution for subcutaneous injection 48 mg in 0.8 mL Epkinly® LICENSED STERILE COMPOUNDERS OF AUSTRALIA LIMITED New PBS listing PBS Section 100 (Efficient Funding of Chemotherapy) WITHDRAWN	Relapsed or refractory diffuse large B-cell lymphoma	To request that the listings for epcoritamab transition to the Section 100 (Efficient Funding of Chemotherapy) program. Authority Required
ESTRADIOL WITH PROGESTERONE Capsule containing estradiol 1mg (as hemihydrate) with progesterone 100mg Bijuva® THERAMEX AUSTRALIA PTY LTD New PBS listing PBS General Schedule	Vasomotor symptoms in post-menopausal women	To consider the sponsor's revised proposal for listing estradiol with progesterone for the treatment of moderate to severe vasomotor symptoms in post-menopausal women. This item was previously recommended by the PBAC at its November 2025 meeting. Unrestricted Benefit for 30-day listing Restricted Benefit for 60-day listing

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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.)
ETONOGESTREL Subcutaneous implant 68 mg Implanon NXT® ORGANON PHARMA PTY LTD Change to existing listing PBS General Schedule	Contraception	To request a revised price for the current listing of etonogestrel for patients requiring contraception. Unrestricted Benefit
EVOLOCUMAB Injection 140 mg in 1 mL single use pre-filled pen Repatha® AMGEN AUSTRALIA PTY LIMITED New PBS listing PBS General Schedule	Non-familial hypercholesterolaemia Familial heterozygous hypercholesterolaemia Familial homozygous hypercholesterolaemia	To request new listings for evolocumab with increased maximum dispensed quantities for all currently listed indications to allow for 60-day prescriptions. Authority Required

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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.)
METHOXSALEN Solution for blood fraction 20 microgram per mL, 10 mL Uvadex® HEALTH TECHNOLOGY ANALYSTS PTY LIMITED Change to existing listing PBS Section 100 (Highly Specialised Drugs Program)	Cutaneous T-cell lymphoma (CTCL) Chronic graft versus host disease (cGVHD)	To request a change to the existing listings for methoxsalen for CTCL and cGVHD to allow consultant or specialist dermatologists to prescribe treatment. Authority Required (STREAMLINED)
TEPROTUMUMAB Powder for I.V. infusion 500 mg Tepezza® AMGEN AUSTRALIA PTY LIMITED New PBS listing PBS Section 100 (Highly Specialised Drugs Program)	Thyroid eye disease (TED)	To consider the sponsor's revised proposal for listing teprotumumab for the treatment of adult patients with active, moderate-to-severe TED who have a clinical activity score (CAS) or three or more for the most severely affected eye. This item was previously recommended by the PBAC at its May 2025 meeting. Authority Required (Telephone/Online) for initial treatment Authority Required (STREAMLINED) for continuing treatment

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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.)
USTEKINUMAB Injection 45 mg in 0.5 mL vial Injection 45 mg in 0.5 mL single use pre-filled pen Injection 90 mg in 1 mL single use pre-filled pen Steqeyma® CELLTRION HEALTHCARE AUSTRALIA PTY LTD New PBS listing PBS General Schedule	Severe chronic plaque psoriasis Severe psoriatic arthritis Severe Crohn disease Complex refractory fistulising Crohn disease Moderate to severe ulcerative colitis	To request listing of new forms of the Steqeyma biosimilar brand of ustekinumab that mirror the originator brand's current listings with equivalent forms and strengths. Authority Required

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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.)
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 Yesintek® GENERIC HEALTH PTY LTD New PBS listing PBS General Schedule PBS Section 100 (Highly Specialised Drugs Program)	Severe chronic plaque psoriasis Severe psoriatic arthritis Severe Crohn disease Complex refractory fistulising Crohn disease Moderate to severe ulcerative colitis	To request listing of a new ustekinumab biosimilar that mirrors the originator brand's current listings. Authority Required

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Version 6

Items added or amended

1. AZACITIDINE (Azacitidine Accord®, Azacitidine Dr Reddy's®, Azacitidine Euglia®, Azacitidine Juno®, Azacitidine MSN®, Azacitidine Sandoz®, Azacitidine SXP®) – To be considered at a future PBAC meeting
2. DARATUMUMAB (Darzalex SC®) – To be considered at a future PBAC meeting

Items added or amended previously

3. APADAMTASE ALFA with CINAXADAMTASE ALFA (recombinant ADAMTS13) – Drug name and Form amended
4. APALUTAMIDE (Erlyand®) – Review of positive PBAC recommendations not accepted by applicants – Added
5. ATEZOLIZUMAB (Tecentriq SC®) – Withdrawn
6. Atomoxetine and guanfacine (Various brands) – To be considered at a future PBAC meeting
7. Azithromycin for the treatment of diphtheria in current outbreak setting (various brands) – Added
8. BIRCH TRITERPENES (Filsuvez®) – Submission held over from the March 2026 PBAC meeting to the July 2026 PBAC meeting – Added
9. BUDESONIDE WITH GLYCOPYRRONIUM AND FORMOTEROL (Breztri Aerosphere®) – Form/strength, Submission type and Purpose amended
10. BUDESONIDE WITH GLYCOPYRRONIUM AND FORMOTEROL (Breztri Aerosphere®) – To be considered at a future PBAC meeting
11. EPCORITAMAB (Epkinly®) – Withdrawn
12. High clinical unmet need (HUCN) and high added therapeutic value (HATV) Project Update – Added
13. LEVODOPA WITH CARBIDOPA AND ENTACAPONE (Lecigon®) – Review of positive PBAC recommendations not accepted by applicants – Added
14. LONCASTUXIMAB TESIRINE (Zynlonta®) – Early re-entry resubmission – Added
15. ODEVIXIBAT (Bylvay®) – Early re-entry resubmission – Added
16. PBAC Guidelines Endorsement and Streamlined Assessment Project Update – Added
17. PBAC Guidelines Endorsement and Streamlined Assessment Project Update – Title and purpose of submission amended
18. PEGCETACOPLAN (Empaveli®) – Early re-entry resubmission – Added
19. PEGVALIASE (Palynziq®) – Submission deferred at March 2026 PBAC meeting – Added
20. Prescribing conditions for lanreotide (Various brands) – Added
21. PROGESTERONE (Ultrogestan®) – Review of positive PBAC recommendations not accepted by applicants – Added
22. Review of designated Registered Nurse prescribing – Added