

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

Closing date for consumer comments 28 May 2025

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

The PBAC agenda consists of the following:

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

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

Pharmaceutical benefits listed in the Schedule fall into three broad categories:

Unrestricted benefits – have no restrictions on their therapeutic uses;

Restricted benefits – can only be prescribed for specific therapeutic uses (noted as Restricted benefit); and

Authority required benefits – Authority required benefits fall into two categories:

1. *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 (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 (Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased.)
ABALOPARATIDE Solution for injection 3 mg in 1.5 mL pre-filled pen Eladynos® THERAMEX AUSTRALIA PTY LTD (New PBS listing)	Osteoporosis	To request a General Schedule Authority Required (Telephone/Online) listing for the first line treatment of severe established osteoporosis.

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<p align="center">ABIRATERONE ACETATE AND PREDNISOLONE</p> <p align="center">Pack containing 56 tablets abiraterone acetate 500 mg and 56 tablets prednisolone 5 mg</p> <p align="center">Andriga-10</p> <p align="center">ACTOR PHARMACEUTICALS PTY LTD</p> <p align="center">(New PBS listing)</p>	<p align="center">Castration resistant metastatic carcinoma of the prostate (mCRPC)</p>	<p align="center">To request a General Schedule Authority Required (Telephone/Online) listing of a composite pack containing abiraterone acetate and prednisolone for the treatment of patients with mCRPC.</p>
<p align="center">ACALABRUTINIB</p> <p align="center">Tablet 100 mg</p> <p align="center">Calquence®</p> <p align="center">ASTRAZENECA PTY LTD</p> <p align="center">(Change to existing listing)</p>	<p align="center">Mantle cell lymphoma (MCL)</p>	<p align="center">To request a General Schedule Authority Required (Telephone/Online) listing in combination with bendamustine and rituximab for patients with previously untreated Stage III or IV MCL who are ineligible for stem cell transplantation.</p>

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<p align="center">AFLIBERCEPT</p> <p>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)</p> <p align="center">Aflir® Enzeevu™</p> <p align="center">SANDOZ PTY LTD</p> <p align="center">(New PBS listing)</p>	<p align="center">Macular oedema secondary to retinal vein occlusion (RVO) Diabetic macular oedema (DMO) Subfoveal choroidal neovascularisation (CNV) secondary to age-related macular degeneration (AMD)</p>	<p align="center">To request General Schedule Authority Required listings of two aflibercept biosimilars for the treatment of RVO, DMO, and CNV due to AMD under the same conditions as their respective reference biologic.</p>
<p align="center">APOMORPHINE</p> <p align="center">Injection containing apomorphine hydrochloride hemihydrate 100 mg in 20 mL</p> <p align="center">Movapo® POD</p> <p align="center">STADA PHARMACEUTICALS AUSTRALIA PTY LIMITED</p> <p align="center">(New PBS listing)</p>	<p align="center">Parkinson disease</p>	<p align="center">To request General Schedule Authority Required (STREAMLINED) and Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listings of Movapo® POD, administered via an infusion pump with a collar attachment, under the existing listings for Apomine Solution for Infusion for the treatment of Parkinson's disease.</p>

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<p align="center">ARIPIPIRAZOLE</p> <p>Powder for injection 300 mg (as monohydrate) with diluent in pre-filled dual-chamber syringe Powder for injection 400 mg (as monohydrate) with diluent in pre-filled dual-chamber syringe</p> <p align="center">Abilify Maintena®</p> <p align="center">LUNDBECK AUSTRALIA PTY LTD</p> <p align="center">(New PBS listing)</p>	<p align="center">Schizophrenia</p>	<p align="center">To request General Schedule Authority Required (STREAMLINED) listings of two new forms for the treatment of schizophrenia.</p>
<p align="center">BRENTUXIMAB VEDOTIN</p> <p align="center">Powder for I.V. infusion 50 mg</p> <p align="center">Adcetris®</p> <p align="center">TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD.</p> <p align="center">(Change to existing listing)</p>	<p align="center">Hodgkin lymphoma</p>	<p align="center">Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (Written) listing for the first line treatment of advanced Hodgkin lymphoma in combination with chemotherapy.</p>

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<p>BREXPIRAZOLE Tablet 500 micrograms Rexulti® LUNDBECK AUSTRALIA PTY LTD (New PBS listing)</p>	<p>Schizophrenia</p>	<p>To request a General Schedule Authority Required (STREAMLINED) listing of a new strength for the treatment of schizophrenia.</p>
<p>BULEVIRTIDE Powder for injection 2 mg Hepcludex® GILEAD SCIENCES PTY LTD (New PBS listing)</p>	<p>Chronic hepatitis D</p>	<p>Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of chronic hepatitis D. This matter was deferred at the March 2025 PBAC Meeting.</p>
<p>CABOZANTINIB Tablet 20 mg Tablet 40 mg Tablet 60 mg Cabometyx® IPSEN PTY LTD (Change to existing listing)</p>	<p>Pancreatic neuroendocrine tumors (pNET) Extra-pancreatic neuroendocrine tumors (epNET)</p>	<p>To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of unresectable locally advanced or metastatic well- or moderately-differentiated pNET or epNET after prior systemic therapy.</p>

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<p>CALCIPOTRIOL WITH BETAMETHASONE DIPROPIONATE</p> <p>Cream containing calcipotriol 50 micrograms with betamethasone 500 micrograms (as dipropionate) per g, 60 g</p> <p align="center">Wynzora®</p> <p>ACTOR PHARMACEUTICALS PTY LTD</p> <p align="center">(New PBS listing)</p>	<p align="center">Chronic stable plaque type psoriasis vulgaris</p>	<p align="center">To request a General Schedule Restricted Benefit listing for the treatment of chronic plaque type psoriasis vulgaris in patients who have not adequately responded to potent topical corticosteroid monotherapy.</p>
<p align="center">CANNABIDIOL</p> <p align="center">Oral liquid 100 mg per mL, 100 mL</p> <p align="center">Epidyolex®</p> <p>JAZZ PHARMACEUTICALS ANZ PTY LTD</p> <p align="center">(Change to existing listing)</p>	<p align="center">Seizures of the Lennox-Gastaut syndrome (LGS)</p>	<p align="center">To request an amendment to the restriction level from Authority Required (Telephone/Online) to Authority Required (STREAMLINED) for the treatment of seizures associated with LGS. The submission also requested amendments to the clinical criteria, including the requirement for a diagnosis confirmed by an electroencephalogram and a definition of the types of seizures, and to the treatment criteria to allow prescribing by a paediatrician.</p>
<p align="center">DONANEMAB</p> <p>Solution concentrate for I.V. infusion 350 mg in 20 mL</p> <p align="center">Kisunla®</p> <p>ELI LILLY AUSTRALIA PTY LTD</p> <p align="center">(New PBS listing)</p>	<p align="center">Early symptomatic Alzheimer's disease</p>	<p align="center">To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Telephone/Online) listing of donanemab for the treatment of patients with early symptomatic Alzheimer's disease.</p>

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<p align="center">DURVALUMAB</p> <p>Solution concentrate for I.V. infusion, 120 mg in 2.4 mL, 500 mg in 10mL</p> <p align="center">Imfinzi®</p> <p align="center">ASTRAZENECA PTY LTD</p> <p align="center">(Change to existing listing)</p>	<p align="center">Small cell lung cancer (SCLC)</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of limited-stage SCLC in patients whose disease has not progressed during or following chemoradiation therapy.</p>

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<p align="center">ENOXAPARIN</p> <p>Injection containing enoxaparin sodium 20 mg (2,000 I.U. anti-Xa) in 0.2 mL pre-filled syringe</p> <p>Injection containing enoxaparin sodium 40 mg (4,000 I.U. anti-Xa) in 0.4 mL pre-filled syringe</p> <p>Injection containing enoxaparin sodium 60 mg (6,000 I.U. anti-Xa) in 0.6 mL pre-filled syringe</p> <p>Injection containing enoxaparin sodium 80 mg (8,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe</p> <p>Injection containing enoxaparin sodium 100 mg (10,000 I.U. anti-Xa) in 1 mL pre-filled syringe</p> <p>Injection containing enoxaparin sodium 120 mg (12,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe</p> <p>Injection containing enoxaparin sodium 150 mg (15,000 I.U. anti-Xa) in 1 mL pre-filled syringe</p> <p align="center">Enoxaject®</p> <p align="center">PHARMACOR PTY LIMITED</p> <p align="center">(New PBS listing)</p>	<p align="center">Prevention of venous thromboembolism (VTE) Treatment of venous thrombosis Prevention of extracorporeal thrombosis during haemodialysis Treatment of acute ST-segment elevation myocardial infarction (STEMI), non-STEMI and unstable angina</p>	<p align="center">To request General Schedule Restricted Benefit listings of a new enoxaparin biosimilar under the same conditions as other enoxaparin brands for the respective forms.</p>

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EPLERENONE Tablet 25 mg Tablet 50 mg Inspra® VIATRIS PTY LTD (Change to existing listing)	Heart failure	To request the PBAC consider an amendment to the clinical criteria for eplerenone to align with clinical guidelines for the management of heart failure.
ETANERCEPT Injections 50 mg in 1 mL single use pre-filled syringes, 4 Nepexto® MAXX PHARMA PTY LTD (New PBS listing)	Severe active rheumatoid arthritis Severe psoriatic arthritis Ankylosing spondylitis Severe chronic plaque psoriasis Juvenile idiopathic arthritis	To request General Schedule Authority Required and Section 100 (Highly Specialised Drugs Program) Authority Required listings of a new etanercept biosimilar under the same conditions as another biosimilar brand of etanercept in the same form for the treatment of severe active rheumatoid arthritis, severe psoriatic arthritis, ankylosing spondylitis, severe chronic plaque psoriasis, and juvenile idiopathic arthritis.
FUTIBATINIB Tablet 4 mg Lytgobi® TAIHO PHARMA OCEANIA PTY LTD (New PBS listing)	Bile duct cancer (cholangiocarcinoma)	Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of patients with locally advanced or metastatic cholangiocarcinoma who have previously progressed on systemic therapy and have a fibroblast growth factor receptor 2 fusion or rearrangement.

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<p align="center">GIVOSIRAN</p> <p align="center">Solution for injection 189 mg in 1 mL</p> <p align="center">Givlaari®</p> <p align="center">MEDISON PHARMA AUSTRALIA PTY LIMITED</p> <p align="center">(New PBS listing)</p>	<p align="center">Acute hepatic porphyria (AHP)</p>	<p align="center">To request a General Schedule Authority Required (Written) listing for the initial treatment and an Authority Required (STREAMLINED) listing for the continuing treatment of AHP in adults and adolescents aged 12 years and older.</p>
<p align="center">GLOFITAMAB</p> <p align="center">Solution concentrate for I.V. infusion 2.5 mg in 2.5 mL</p> <p align="center">Solution concentrate for I.V. infusion 10 mg in 10 mL</p> <p align="center">Columvi®</p> <p align="center">ROCHE PRODUCTS PTY LTD</p> <p align="center">(New PBS listing)</p>	<p align="center">Relapsed or refractory diffuse large B-cell lymphoma (RR DLBCL)</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for the treatment of patients with RR DLBCL.</p>

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<p align="center">GUSELKUMAB</p> <p>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,</p> <p align="center">Tremfya®</p> <p align="center">JANSSEN-CILAG PTY LTD</p> <p align="center">(New PBS listing)</p>	<p align="center">Severe Crohn disease</p>	<p align="center">To request General Schedule Authority Required (Written) listings for subcutaneous injection and a Section 100 (Highly Specialised Drug Program) Authority Required (Written) listing for I.V. infusion for the treatment of severe Crohn disease.</p>
<p align="center">INCOBOTULINUMTOXINA</p> <p>Lyophilised powder for injection 100 units</p> <p align="center">Xeomin®</p> <p align="center">MERZ AUSTRALIA PTY LTD</p> <p align="center">(Change to existing listing)</p>	<p align="center">Moderate to severe spasticity of the upper limb Dynamic equinus foot deformity</p>	<p align="center">To request a Section 100 (Botulinum Toxin Program) Authority Required (STREAMLINED) listing for the treatment of spasticity of the lower and/or upper limbs associated with cerebral palsy in patients aged 2 years and older.</p>

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<p align="center">INFLIXIMAB</p> <p align="center">Powder for I.V. infusion 100 mg</p> <p align="center">Remsima®</p> <p align="center">CELLTRION HEALTHCARE AUSTRALIA PTY LTD</p> <p align="center">(New PBS listing)</p>	<p>Severe active rheumatoid arthritis</p> <p>Ankylosing spondylitis</p> <p>Severe psoriatic arthritis</p> <p>Severe chronic plaque psoriasis</p> <p>Severe Crohn disease</p> <p>Complex refractory fistulising Crohn Disease</p> <p>Moderate to severe ulcerative colitis</p>	<p align="center">To request Section 100 (Highly Specialised Drugs Program) Authority Required listings of a new infliximab biosimilar under the same conditions as other biosimilar brands of infliximab.</p>
<p align="center">INFLUENZA VACCINE</p> <p align="center">Injection 0.5 mL</p> <p align="center">Fluad®</p> <p align="center">Injection 0.5 mL</p> <p align="center">Flucelvax®</p> <p align="center">SEQIRUS (AUSTRALIA) PTY LTD</p> <p align="center">(New NIP listing)</p> <p align="center">WITHDRAWN</p>	<p align="center">Prevention of influenza</p>	<p align="center">To request National Immunisation Program (NIP) listings of inactivated trivalent influenza vaccines (TIVs), Fluad® (adjuvanted TIV) for patients aged 65 years and older, and Flucelvax® (cell-based TIV) for patients aged 6 months and older, for the prevention of influenza in the same eligible patients as the currently NIP-listed quadrivalent influenza vaccine (QIV) formulations.</p>

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INSULIN DEGLUDEC Solution for injection 100 units per mL Tresiba® Penfill® NOVO NORDISK PHARMACEUTICALS PTY. LIMITED (New PBS listing)	Type 1 diabetes mellitus (T1DM)	Resubmission to request a General Schedule Restricted Benefit listing for the treatment of T1DM.
LENIOLISIB Tablet 70 mg Joenja® PHARMING AUSTRALIA PTY LTD (New PBS listing)	Activated PI3K delta syndrome (APDS)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of symptomatic APDS in adults and adolescents aged 12 years and older .

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<p>Life Saving Drugs Program (LSDP) medicines for Gaucher disease (type 1)</p> <p align="center">ELIGLUSTAT</p> <p>Capsule containing eliglustat tartrate, 100 mg</p> <p align="center">Cerdelga®</p> <p align="center">IMIGLUCERASE</p> <p>Powder for IV infusion, 400 units</p> <p align="center">Cerezyme®</p> <p align="center">TALIGLUCERASE ALFA</p> <p>Powder for IV infusion, 200 units</p> <p align="center">Elelyso®</p> <p align="center">VELAGLUCERASE ALFA</p> <p>Powder for IV infusion, 400 units</p> <p align="center">Vpriv®</p> <p>Various sponsors</p> <p>(New PBS listing)</p>	<p align="center">Gaucher disease (type 1) (GD1)</p>	<p align="center">To consider a referral from the LSDP Expert Panel seeking reconsideration of listing medicines for the treatment of GD1 on the PBS.</p>

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<p>Life Saving Drugs Program (LSDP) medicines for hereditary tyrosinaemia type 1</p> <p align="center">NITISINONE</p> <p align="center">Capsule 2 mg Capsule 5 mg Capsule 10 mg Capsule 20 mg Oral suspension 4 mg per mL, 90 mL</p> <p align="center">Orfadin®</p> <p>A.MENARINI AUSTRALIA PTY LIMITED</p> <p align="center">Tablet 2 mg Tablet 5 mg Tablet 10 mg</p> <p align="center">Nityr™</p> <p align="center">ORPHARMA PTY LTD</p> <p align="center">(New PBS listing)</p>	<p align="center">Hereditary tyrosinaemia type 1 (HT-1)</p>	<p align="center">To consider a referral from the LSDP Expert Panel seeking reconsideration of listing nitisinone for the treatment of HT-1 on the PBS.</p>

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<p>METHADONE Tablet 5 mg Methadone-AFT AFT PHARMACEUTICALS (AU) PTY LTD (New PBS listing)</p>	<p>Chronic severe disabling pain</p>	<p>To request a Palliative Care Authority Required (Telephone/Online) listing and a General Schedule Authority Required (STREAMLINED) listing of a new strength under the same conditions as the currently listed strength of methadone tablet for the management of severe disabling pain.</p>
<p>MIRVETUXIMAB SORAVTANSINE Solution for I.V. infusion 100 mg in 20 mL vial Elahere® ABBVIE PTY LTD (New PBS listing)</p>	<p>Epithelial ovarian, fallopian tube or primary peritoneal cancer</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for the treatment of high grade epithelial ovarian, fallopian tube or primary peritoneal cancer in patients who have platinum-resistant disease and high folate receptor alpha (FRα) expression.</p>
<p>NEMOLIZUMAB Powder for injection containing nemolizumab 30 mg with diluent in pre-filled dual-chamber pen Nemluvio® GALDERMA AUSTRALIA PTY LTD (New PBS listing)</p>	<p>Atopic dermatitis</p>	<p>To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of patients with severe atopic dermatitis affecting the whole body, face, and/or hands.</p>

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

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<p align="center">NIVOLUMAB</p> <p>Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL</p> <p align="center">Opdivo®</p> <p align="center">IPILIMUMAB</p> <p>Injection concentrate for I.V. infusion 50 mg in 10 mL Injection concentrate for I.V. infusion 200 mg in 40 mL</p> <p align="center">Yervoy®</p> <p align="center">BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD</p> <p align="center">(Change to existing listing)</p>	<p align="center">Advanced (unresectable) Barcelona Clinic Liver Cancer Stage A, Stage B or Stage C hepatocellular carcinoma (HCC)</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first line treatment of advanced (unresectable) HCC.</p>

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<p align="center">NIVOLUMAB</p> <p>Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL</p> <p align="center">Opdivo®</p> <p align="center">IPILIMUMAB</p> <p>Injection concentrate for I.V. infusion 50 mg in 10 mL</p> <p align="center">Yervoy®</p> <p align="center">BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD</p> <p align="center">(Change to existing listing)</p>	<p align="center">Unresectable or metastatic colorectal cancer (mCRC)</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first line treatment of microsatellite instability high or mismatch repair deficient mCRC.</p>

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<p align="center">NIVOLUMAB</p> <p>Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL</p> <p align="center">Opdivo®</p> <p align="center">IPILIMUMAB</p> <p>Injection concentrate for I.V. infusion 50 mg in 10 mL Injection concentrate for I.V. infusion 200 mg in 40 mL</p> <p align="center">Yervoy®</p> <p align="center">Bristol-Myers Squibb Australia Pty Ltd</p> <p align="center">(Change to existing listing)</p>	<p align="center">Unresectable advanced and metastatic cancer</p>	<p align="center">To consider a proposal for an expanded listing to facilitate broad access for unresectable advanced and metastatic cancer.</p>
<p align="center">OCRELIZUMAB</p> <p>Solution for subcutaneous injection 920 mg in 23 mL</p> <p align="center">Ocrevus®</p> <p align="center">ROCHE PRODUCTS PTY LTD</p> <p align="center">(New PBS listing)</p>	<p align="center">Relapsing-remitting multiple sclerosis (RRMS)</p>	<p align="center">To request Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listings of a new form for the treatment of RRMS.</p>

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<p align="center">ODEVIXIBAT</p> <p align="center">Capsule 200 micrograms Capsule 400 micrograms Capsule 600 micrograms Capsule 1200 micrograms</p> <p align="center">Bylvay®</p> <p align="center">IPSEN PTY LTD</p> <p align="center">(New PBS listing)</p>	<p align="center">Progressive familial intrahepatic cholestasis (PFIC)</p>	<p align="center">Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of PFIC. This matter was deferred at the March 2025 PBAC Meeting.</p>
<p align="center">OSIMERTINIB</p> <p align="center">Tablet 40 mg Tablet 80 mg</p> <p align="center">Tagrisso®</p> <p align="center">ASTRAZENECA PTY LTD</p> <p align="center">(Change to existing listing)</p>	<p align="center">Unresectable locally advanced (Stage III) non-small cell lung cancer (NSCLC)</p>	<p align="center">To request a General Schedule Authority Required (Telephone/Online) listing of osimertinib as monotherapy for the treatment of patients with unresectable, locally advanced (Stage III) epidermal growth factor receptor (EGFR) mutation positive NSCLC whose disease has not progressed during or following platinum-based chemoradiation therapy.</p>

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<p align="center">PALIPERIDONE</p> <p>I.M. injection (modified release) 25 mg (as palmitate) in pre-filled syringe I.M. injection (modified release) 50 mg (as palmitate) in pre-filled syringe I.M. injection (modified release) 75 mg (as palmitate) in pre-filled syringe I.M. injection (modified release) 100 mg (as palmitate) in pre-filled syringe I.M. injection (modified release) 150 mg (as palmitate) in pre-filled syringe</p> <p align="center">Paljuna Monthly</p> <p align="center">JUNO PHARMACEUTICALS PTY LTD</p> <p align="center">(New PBS listing)</p>	<p align="center">Schizophrenia</p>	<p align="center">To request General Schedule Authority Required (STREAMLINED) listings of a new generic brand of paliperidone monthly long-acting injection for the maintenance treatment of schizophrenia.</p>

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<p align="center">PALOPEGTERIPARATIDE</p> <p>Solution for subcutaneous injection 168 micrograms in 0.56 mL pre-filled pen Solution for subcutaneous injection 294 micrograms in 0.98 mL pre-filled pen Solution for subcutaneous injection 420 micrograms in 1.4 mL pre-filled pen</p> <p align="center">Yorvipath®</p> <p align="center">SPECIALISED THERAPEUTICS PHARMA PTY LTD</p> <p align="center">(New PBS listing)</p>	<p align="center">Chronic hypoparathyroidism</p>	<p align="center">Resubmission to request a General Schedule Authority Required (Telephone/Online) listing for the treatment of chronic hypoparathyroidism.</p>
<p align="center">PEGUNIGALSIDASE ALFA</p> <p>Solution for I.V. injection 20 mg in 10 mL vial</p> <p align="center">Elfabrio®</p> <p align="center">CHIESI AUSTRALIA PTY LTD</p> <p align="center">(New PBS listing)</p>	<p align="center">Fabry disease</p>	<p align="center">To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of Fabry disease.</p>

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<p align="center">PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p align="center">Keytruda®</p> <p align="center">MERCK SHARP & DOHME (AUSTRALIA) PTY LTD</p> <p align="center">(Change to existing listing)</p>	<p align="center">Endometrial cancer</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for pembrolizumab in combination with platinum-based chemotherapy, followed by pembrolizumab monotherapy, for primary advanced or recurrent endometrial cancer, regardless of mismatch repair status.</p>
<p align="center">PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p align="center">Keytruda®</p> <p align="center">Merck Sharp & Dohme (Australia) Pty Ltd</p> <p align="center">(Change to existing listing)</p>	<p align="center">Unresectable advanced and metastatic cancer</p>	<p align="center">To consider a proposal for an expanded listing to facilitate broad access for unresectable advanced and metastatic cancer.</p>

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<p align="center">PIOGLITAZONE</p> <p>Tablet 15 mg (as hydrochloride) Tablet 30 mg (as hydrochloride) Tablet 45 mg (as hydrochloride)</p> <p align="center">Actos®</p> <p align="center">CELLTRION HEALTHCARE AUSTRALIA PTY LTD</p> <p align="center">(New PBS listing)</p> <p align="center">TO BE CONSIDERED AT THE MAY 2025 PBAC MEETING</p>	<p align="center">Type 2 diabetes mellitus (T2DM)</p>	<p>To request General Schedule Restricted Benefit listings for a new pack size of pioglitazone (Actos®), with an increased maximum quantity across all currently PBS-listed strengths of pioglitazone for the treatment of T2DM.</p>
<p align="center">RESPIRATORY SYNCYTIAL VIRUS VACCINE</p> <p>Powder and suspension for injection (0.5 mL)</p> <p align="center">Arexvy®</p> <p align="center">GLAXOSMITHKLINE AUSTRALIA PTY LTD</p> <p align="center">(New NIP listing)</p>	<p align="center">Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)</p>	<p>Resubmission to request a National Immunisation Program (NIP) listing for the prevention of lower respiratory tract disease caused by RSV in older adults.</p>

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RIBOCICLIB Tablet 200 mg Kisqali® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED (Change to existing listing)	Hormone receptor positive (HR+) and human epidermal growth factor receptor 2 negative (HER2-) early breast cancer	To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of patients with HR+/HER2- resected, Stage II or III early breast cancer at high risk of recurrence.
SELADELPAR Capsule 10 mg Livdelzi® GILEAD SCIENCES PTY LTD (New PBS listing)	Primary biliary cholangitis (PBC)	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of PBC in patients who have had an inadequate response to first line therapy with ursodeoxycholic acid (UDCA) or are intolerant to UDCA.
TACROLIMUS Ointment 1 mg per g, 30 g aZematop® ARROTEX PHARMACEUTICALS PTY LTD (New PBS listing)	Atopic dermatitis	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of moderate to severe atopic dermatitis.

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<p>TARLATAMAB</p> <p>Powder for injection 10 mg</p> <p>Imdelltra®</p> <p>AMGEN AUSTRALIA PTY LTD</p> <p>(New PBS listing)</p> <p>WITHDRAWN</p>	<p>Small cell lung cancer</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of patients with extensive-stage small-cell lung cancer with disease progression after platinum-based chemotherapy and at least one other line of therapy (i.e. third-line therapy or thereafter).</p>
<p>TERIPARATIDE</p> <p>Injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled pen</p> <p>Ritosa®</p> <p>SUN PHARMA ANZ PTY LTD</p> <p>(New PBS listing)</p>	<p>Osteoporosis</p>	<p>To request a General Schedule Authority Required (STREAMLINED) listing under the same conditions as the currently listed brands of teriparatide for the treatment of severe established osteoporosis.</p>

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<p align="center">TIRZEPATIDE</p> <p>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</p> <p align="center">Mounjaro®</p> <p>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</p> <p align="center">Mounjaro® KwikPen®</p> <p align="center">ELI LILLY AUSTRALIA PTY LTD</p> <p align="center">(New PBS listing)</p>	<p align="center">Type 2 diabetes mellitus (T2DM)</p>	<p align="center">Resubmission to request a General Schedule Authority Required (Telephone/Online) listing for the treatment of adults with inadequately controlled T2DM.</p>
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<p>VANZACAFITOR WITH TEZACAFITOR AND WITH DEUTIVACAFITOR</p> <p>Pack containing 84 tablets vanzacaftor 4 mg with tezacaftor 20 mg and with deutivacaftor 50 mg</p> <p>Pack containing 56 tablet vanzacaftor 10 mg with tezacaftor 50 mg and with deutivacaftor 125 mg</p> <p align="center">Alyftrek®</p> <p>VERTEX PHARMACEUTICALS PTY LTD</p> <p align="center">(New PBS listing)</p>	<p align="center">Cystic fibrosis</p>	<p align="center">To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of cystic fibrosis in patients who are aged 6 years and older and who have at least one F508del mutation or another responsive mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.</p>
<p>VELMANASE ALPHA</p> <p>Powder for I.V. infusion 10 mg</p> <p align="center">Lamzede®</p> <p>CHIESI AUSTRALIA PTY LTD</p> <p align="center">(New PBS listing)</p>	<p align="center">Alpha- mannosidosis</p>	<p align="center">To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing as an enzyme replacement therapy for the treatment of non-neurological manifestations in patients with alpha-mannosidosis.</p>

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<p>VORASIDENIB</p> <p>Tablet 10 mg Tablet 40 mg</p> <p>Voranigo®</p> <p>SERVIER LABORATORIES (AUST.) PTY. LTD.</p> <p>(New PBS listing)</p>	<p>Astrocytoma or oligodendroglioma</p>	<p>To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of isocitrate dehydrogenase-mutant astrocytoma or oligodendroglioma.</p>
<p>ATEZOLIZUMAB</p> <p>Solution concentrate for I.V. infusion 840 mg in 14 mL Solution concentrate for I.V. infusion 1200 mg in 20 mL</p> <p>Tecentriq®</p> <p>Solution for subcutaneous injection 1875 mg in 15 mL</p> <p>Tecentriq® SC</p> <p>ROCHE PRODUCTS PTY LTD</p> <p>(Sub-committee report DUSC analysis)</p>	<p>Hepatocellular carcinoma</p>	<p>To assess the utilisation of PBS listed atezolizumab for advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma.</p>

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<p align="center">CEMIPLIMAB</p> <p>Solution concentrate for I.V. infusion 350 mg in 7 mL</p> <p align="center">Libtayo®</p> <p>MEDISON PHARMA AUSTRALIA PTY LTD</p> <p align="center">(Sub-committee report DUSC analysis)</p>	<p align="center">Metastatic or locally advanced cutaneous squamous cell carcinoma</p>	<p align="center">To assess the utilisation of PBS listed cemiplimab for metastatic or locally advanced cutaneous squamous cell carcinoma.</p>
<p align="center">NIVOLUMAB</p> <p>Injection concentrate for I.V. infusion 40 mg in 4 mL</p> <p>Injection concentrate for I.V. infusion 100 mg in 10 mL</p> <p align="center">Opdivo®</p> <p>BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD</p> <p align="center">(Sub-committee report DUSC analysis)</p>	<p align="center">Advanced or metastatic gastro-oesophageal cancers</p>	<p align="center">To assess the utilisation of PBS listed nivolumab for advanced or metastatic gastro-oesophageal cancers.</p>

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NUSINERSEN Solution for injection 12 mg in 5 mL Spinraza® BIOGEN AUSTRALIA PTY LTD (Sub-committee report DUSC analysis)	Spinal muscular atrophy	To assess the utilisation of PBS listed nusinersen for spinal muscular atrophy in adult patients.
Transition existing quadrivalent influenza formulations to trivalent formulations Injection (0.5 mL) Various brands Various sponsors (Other matters)	Prevention of influenza	To request advice from the PBAC on varying the <i>National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No. 1)</i> to transition existing quadrivalent influenza vaccine formulations to trivalent formulations.
TRIGLYCERIDES, MEDIUM CHAIN Oil 500 mL (MCT Oil) MCT Oil NUTRICIA AUSTRALIA PTY LIMITED (Other matters)	Chylous ascites Chylothorax Fat malabsorption Hyperlipoproteinaemia type 1 Intractable childhood epilepsy Cerebrospinal fluid glucose transporter defect Long chain fatty acid oxidation disorders	To request an increase in the maximum quantity of MCT Oil for all PBS-listed indications.

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<p>TRIGLYCERIDES - MEDIUM CHAIN, FORMULA</p> <p>Oral powder 400 g (Monogen)</p> <p>Monogen®</p> <p>NUTRICIA AUSTRALIA PTY LIMITED</p> <p>(Other matters)</p>	<p>Dietary management of conditions requiring a source of medium chain triglycerides</p> <p>Hyperlipoproteinaemia type 1</p> <p>Long chain fatty acid oxidation disorders</p> <p>Chylous ascites</p> <p>Chylothorax</p>	<p>To request an increase in the maximum quantity of Monogen for all PBS-listed indications.</p>
<p>CARMELLOSE WITH GLYCEROL AND HYALURONIC ACID</p> <p>Eye drops containing carmellose sodium 5 mg with glycerol 9 mg and sodium hyaluronate 1 mg per mL</p> <p>Optive Fusion®</p> <p>ABBVIE PTY LTD</p> <p>(Review of positive PBAC recommendations not accepted by applicants)</p>	<p>Severe dry eye syndrome</p>	<p>To request the PBAC review its May 2023 recommendation that has not yet been accepted by the applicant.</p>

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<p align="center">GALCANEZUMAB</p> <p align="center">Injection 120 mg in 1 mL pre-filled pen</p> <p align="center">Emgality®</p> <p align="center">ELI LILLY AUSTRALIA PTY LTD</p> <p align="center">(Review of positive PBAC recommendations not accepted by applicants)</p>	<p align="center">Treatment-resistant high frequency episodic migraine</p>	<p align="center">To request the PBAC review its March 2022 recommendation that has not yet been accepted by the applicant.</p>
<p align="center">HYALURONIC ACID WITH POLYETHYLENE GLYCOL 400 WITH PROPYLENE GLYCOL WITH HYDROXYPROPYL GUAR</p> <p align="center">Eye drops containing sodium hyaluronate 1.5 mg per mL with polyethylene glycol 400, propylene glycol and hydroxypropyl guar, 10 mL</p> <p align="center">Systane® Hydration</p> <p align="center">ALCON LABORATORIES (AUSTRALIA) PTY LTD</p> <p align="center">(Review of positive PBAC recommendations not accepted by applicants)</p>	<p align="center">Severe dry eye syndrome</p>	<p align="center">To request the PBAC review its May 2023 recommendation that has not yet been accepted by the applicant.</p>

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

Closing date for consumer comments 28 May 2025

Drug Name, form(s), strength(s) and Sponsor, Submission type (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 (Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased.)
<p align="center">MIRIKIZUMAB</p> <p>Solution concentrate for I.V. infusion 300 mg in 15 mL Solution for injection 100 mg in 1 mL pre-filled pen</p> <p align="center">Omvoh®</p> <p align="center">ELI LILLY AUSTRALIA PTY LTD</p> <p>(Review of positive PBAC recommendations not accepted by applicants)</p>	<p align="center">Ulcerative colitis</p>	<p align="center">To request the PBAC review its July 2023 recommendation that has not yet been accepted by the applicant.</p>
<p align="center">MOBOCERTINIB</p> <p align="center">Capsule 400 mg</p> <p align="center">Exkivity®</p> <p align="center">TAKEDA PHARMACEUTICALS AUSTRALIA PTY LTD</p> <p>(Review of positive PBAC recommendations not accepted by applicants)</p>	<p align="center">Non-small cell lung cancer</p>	<p align="center">To request the PBAC review its July 2023 recommendation that has not yet been accepted by the applicant.</p>

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Closing date for consumer comments 28 May 2025

<p align="center">Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p align="center">Drug Type and Use (What is the drug used to treat?)</p>	<p align="center">Listing requested by Sponsor / Purpose of Submission (Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased.)</p>
<p align="center">SECUKINUMAB</p> <p>Solution for injection 300 mg in 2 mL pre-filled pen Solution for injection 300 mg in 2 mL pre-filled syringe</p> <p align="center">Cosentyx®</p> <p align="center">NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED</p> <p>(Review of positive PBAC recommendations not accepted by applicants)</p>	<p align="center">Non-radiographic axial spondyloarthritis Severe active psoriatic arthritis Severe psoriatic arthritis Ankylosing spondylitis Active ankylosing spondylitis Severe chronic plaque psoriasis</p>	<p align="center">To request the PBAC review its March 2022 recommendation that has not yet been accepted by the applicant.</p>
<p align="center">SOMAPACITAN</p> <p>Injection 5 mg in 1.5 mL pre-filled pen Injection 10 mg in 1.5 mL pre-filled pen Injection 15 mg in 1.5 mL pre-filled pen</p> <p align="center">Sogroya®</p> <p align="center">NOVO NORDISK PHARMACEUTICALS PTY LIMITED</p> <p>(Review of positive PBAC recommendations not accepted by applicants)</p> <p align="center">WITHDRAWN</p>	<p align="center">Paediatric patients with growth hormone deficiency</p>	<p align="center">To request the PBAC review its July 2023 recommendation that has not yet been accepted by the applicant.</p>

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July 2025 PBAC MEETING**

Closing date for consumer comments 28 May 2025

<p align="center">Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p align="center">Drug Type and Use (What is the drug used to treat?)</p>	<p align="center">Listing requested by Sponsor / Purpose of Submission (Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased.)</p>
<p align="center">SOMAPACITAN</p> <p align="center">Injection 10 mg in 1.5 mL pre-filled pen</p> <p align="center">Sogroya®</p> <p align="center">NOVO NORDISK PHARMACEUTICALS PTY LIMITED</p> <p align="center">(Review of positive PBAC recommendations not accepted by applicants)</p>	<p align="center">Adult-onset growth hormone deficiency</p>	<p align="center">To request the PBAC review its March 2022 recommendation that has not yet been accepted by the applicant.</p>
<p align="center">Review of PBS-listed medicines for nurse practitioner prescribing</p> <p align="center">Various forms and strengths</p> <p align="center">Various brands</p> <p align="center">Various sponsors</p> <p align="center">(Other matters)</p>	<p align="center">Various</p>	<p align="center">To request the PBAC consider a tranche of PBS-listed medicines which do not include nurse practitioners as authorised prescribers but may be suitable for prescribing by these health professionals.</p>

Version 5

Items added or amended

1. ARIPIPRAZOLE (Abilify Maintena®) – Form(s) amended
2. BULEVIRTIDE (Hepcludex®) – Added
3. EPLERENONE (Inspra®) – Sponsor amended
4. Life Saving Drugs Program (LSDP) medicines for Gaucher disease (type 1) – Forms and trade names amended
5. Life Saving Drugs Program (LSDP) medicines for hereditary tyrosinaemia type 1 – Drug names, forms, and trade names amended
6. ODEVIXIBAT (Bylvay®) – Added
7. Review of PBS-listed medicines for nurse practitioner prescribing (Various brands) – Added
8. SOMAPACITAN (Sogroya®, Paediatric patients with growth hormone deficiency) – Review of positive PBAC recommendations not accepted by applicants – Withdrawn
9. TARLATAMAB (Imdeltra®) – Withdrawn

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

Closing date for consumer comments 28 May 2025

Items added or amended previously

10. CARMELLOSE WITH GLYCEROL AND HYALURONIC ACID (Optive Fusion[®]) – Review of positive PBAC recommendations not accepted by applicants – Added
11. CANNABIDIOL (Epidyolex[®]) – Purpose of submission amended
12. FUTIBATINIB (Lytgobi[®]) – Added
13. GALCANEZUMAB (Emgality[®]) – Review of positive PBAC recommendations not accepted by applicants – Added
14. HYALURONIC ACID WITH POLYETHYLENE GLYCOL 400 WITH PROPYLENE GLYCOL WITH HYDROXYPROPYL GUAR (Systane[®] Hydration) – Review of positive PBAC recommendations not accepted by applicants – Added
15. INFLUENZA VACCINE (Fluad[®], Flucelvax[®]) – Withdrawn
16. Life Saving Drugs Program (LSDP) medicines for Gaucher disease (type 1) – Added
17. Life Saving Drugs Program (LSDP) medicines for hereditary tyrosinaemia type 1 – Added
18. MIRIKIZUMAB (Omvoh[®]) – Review of positive PBAC recommendations not accepted by applicants – Added
19. MOBOCERTINIB (Exkivity[®]) – Review of positive PBAC recommendations not accepted by applicants – Added
20. NIVOLUMAB (Opdivo[®]) + IPILIMUMAB (Yervoy[®]) – Unresectable advanced and metastatic cancer – Added
21. PALOPEGTERIPARATIDE (Yorvipath[®]) – Added
22. PEMBROLIZUMAB (Keytruda[®]) – Unresectable advanced and metastatic cancer – Added
23. PIOGLITAZONE (Actos[®]) – To be considered at the May 2025 PBAC meeting
24. SECUKINUMAB (Cosentyx[®]) – Review of positive PBAC recommendations not accepted by applicants – Added
25. SOMAPACITAN (Sogroya[®], Paediatric patients with growth hormone deficiency) – Review of positive PBAC recommendations not accepted by applicants – Added
26. SOMAPACITAN (Sogroya[®], Adult-onset growth hormone deficiency) – Review of positive PBAC recommendations not accepted by applicants – Added
27. Transition existing quadrivalent influenza vaccine formulations to trivalent formulations (Various brands) – Added
28. TRIGLYCERIDES, MEDIUM CHAIN (MCT Oil) – Form amended
29. TRIGLYCERIDES, MEDIUM CHAIN (MCT Oil) – Submission type amended
30. TRIGLYCERIDES - MEDIUM CHAIN, FORMULA (Monogen[®]) – Added