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

Closing date for consumer comments 29 January 2025

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

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

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

Pharmaceutical benefits listed in the Schedule fall into three broad categories:
Unrestricted benefits – have no restrictions on their therapeutic uses;
Restricted benefits – can only be prescribed for specific therapeutic uses (noted as Restricted benefit); and
Authority required benefits – Authority required benefits fall into two categories:

- *Authority required benefits* require prior approval from Services Australia or the DVA (noted as Authority required)
- *Authority required (STREAMLINED) benefits* do not require prior approval from Services Australia or the DVA but require the recording of a streamlined authority code (noted as Authority required (STREAMLINED)).

Initial submissions are categorised broadly as:

- *Category 1 or 2:* Submissions to list new medicines on the Schedule of Pharmaceutical Benefits or to make substantial changes to current listings are generally classified as Category 1 or 2 submissions. These submissions require presentation of an economic evaluation.

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- *Category 3 or 4:* Submissions that relate to new forms of previously listed products and changes to the conditions of use e.g. change in maximum quantity/repeats or clarifying the wording of a restriction (while not altering the intended use) are considered to be Category 3 or 4 submissions. These submissions do not usually require the presentation of an economic evaluation.

Resubmissions are categorised broadly as Standard Re-entry Pathway, Early Resolution Pathway, Early Re-entry Pathway or Facilitated Resolution Pathway. Submission categories and resubmission pathways are outlined in the Procedure Guidance.

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

Drug Name, form(s), strength(s) and Sponsor, Submission type (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.)
AMIVANTAMAB Solution concentrate for I.V. infusion 350 mg in 7 mL Rybrevant® LAZERTINIB Tablet 80 mg (as mesylate monohydrate) Tablet 240 mg (as mesylate monohydrate) Lazcluze® JANSSEN-CILAG PTY LTD (New PBS listing)	Non-small cell lung cancer (NSCLC)	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for amivantamab and a General Schedule Authority Required (Telephone/Online) listing for lazertinib for the first line treatment of patients with epidermal growth factor receptor mutated locally advanced or metastatic (Stage IIIB-IV) NSCLC.

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BULEVIRTIDE Powder for injection 2 mg Hepcludex® GILEAD SCIENCES PTY LTD (New PBS listing)	Chronic hepatitis D	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of chronic hepatitis D.
CIPAGLUCOSIDASE ALFA Powder for I.V. infusion 105 mg Pombiliti® MIGLUSTAT Capsule 65 mg Opfolda® AMICUS THERAPEUTICS PTY LTD (New PBS listing)	Late onset Pompe disease	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of late onset Pompe disease.

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DABRAFENIB Capsule 50 mg (as mesilate) Capsule 75 mg (as mesilate) Tafinlar® TRAMETINIB Tablet 500 micrograms Tablet 2 mg Mekinist® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LTD (Change to existing listing)	Non-small cell lung cancer (NSCLC)	To request a General Schedule Authority Required (STREAMLINED) listing of dabrafenib in combination with trametinib for the treatment of adult patients with BRAF V600E mutation positive advanced or metastatic NSCLC.
DAPSONE Tablet 50 mg Dapsomed® MEDSURGE HEALTHCARE PTY LTD (New PBS listing)	Dermatitis herpetiformis Leprosy Actinomycotic mycetoma	To request a General Schedule Unrestricted Benefit listing of a new strength under the same conditions as the currently listed strengths of dapsone.

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DARATUMUMAB Solution for I.V. infusion 100 mg in 5 mL vial Solution for I.V. infusion 400 mg in 20 mL vial Solution for S.C. injection 1,800 mg in 15 mL vial Darzalex® JANSSEN-CILAG PTY LTD (Change to existing listing)	Multiple myeloma	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (Telephone/Online) listing for the I.V. and S.C. formulations and a General Schedule Authority Required (Telephone/Online) listing for the S.C. formulation for use in combination with lenalidomide and dexamethasone for the treatment of transplant ineligible, newly diagnosed multiple myeloma.
DENOSUMAB Injection 120 mg in 1 mL single use pre-filled syringe Xgeva® AMGEN AUSTRALIA PTY LIMITED (New PBS listing)	Giant cell tumour of bone Bone metastases	To request General Schedule Authority Required (STREAMLINED) listings of a new form for the treatment of giant cell tumour of bone and bone metastases.

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DUPILUMAB Injection 200 mg in 1.14 mL single dose pre-filled pen Injection 300 mg in 2 mL single dose pre-filled pen Dupixent® SANOFI-AVENTIS AUSTRALIA PTY LTD (New PBS listing)	Severe atopic dermatitis Uncontrolled severe asthma	To request the extension of two new forms to a General Schedule Authority Required listing for the treatment of severe atopic dermatitis in patients aged less than 12 years and a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of uncontrolled severe asthma in patients aged 6 to 11 years.
EFGARTIGIMOD ALFA Solution concentrate of I.V. infusion 400 mg in 20 mL Vyvgart® ARGENX AUSTRALIA PTY LTD (New PBS listing)	Generalised myasthenia gravis (gMG)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of adult patients with gMG who are anti-acetylcholine receptor antibody positive.
EFLORNITHINE Tablet 192 mg (as hydrochloride) Ifinwil® NORGINE PTY LTD (New PBS listing)	Neuroblastoma	To request a General Schedule Authority Required (Written) listing for the treatment of high-risk neuroblastoma.

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ELACESTRANT Tablet 86 mg (as dihydrochloride) Tablet 345 mg (as dihydrochloride) Orserdu® A. MENARINI AUSTRALIA PTY LTD (New PBS listing)	Estrogen receptor-positive (ER+) human epidermal growth factor receptor 2-negative (HER2-) locally advanced or metastatic breast cancer	To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of ER+/HER2- locally advanced or metastatic breast cancer in patients who have progressed following at least one line of endocrine therapy administered with a cyclin dependent kinase 4/6 inhibitor and have a confirmed estrogen receptor 1 variant.
ELAFIBRANOR Tablet 80 mg Iqirvo® IPSEN PTY LTD (New PBS listing)	Primary Biliary Cholangitis (PBC)	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of PBC.

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ELEXACAFTOR WITH TEZACAFTOR AND WITH IVACAFTOR, AND IVACAFTOR Pack containing 56 tablets elexacaftor 100 mg with tezacaftor 50 mg and with ivacaftor 75 mg and 28 tablets ivacaftor 150 mg Pack containing 56 tablets elexacaftor 50 mg with tezacaftor 25 mg and with ivacaftor 37.5 mg and 28 tablets ivacaftor 75 mg Pack containing 28 sachets elexacaftor 100 mg with tezacaftor 50 mg and with ivacaftor 75 mg and 28 sachets ivacaftor 75 mg Pack containing 28 sachets elexacaftor 80 mg with tezacaftor 40 mg and with ivacaftor 60 mg and 28 sachets ivacaftor 59.5 mg Trikafta® VERTEX PHARMACEUTICALS (AUSTRALIA) PTY LTD (Change to existing listing)	Cystic fibrosis (CF)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of CF patients aged 2 years or older who have at least one mutation in the CF transmembrane conductance regulator gene responsive to Trikafta® based on clinical and/or in vitro assay data.

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ELRANATAMAB Solution for subcutaneous injection 44 mg in 1.1 mL (40 mg per mL) Solution for subcutaneous injection 76 mg in 1.9 mL (40 mg per mL) Elrexfio® PFIZER AUSTRALIA PTY LTD (New PBS listing)	Relapsed or refractory multiple myeloma (RRMM)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for the treatment of RRMM in patients who have received at least three prior lines of therapy.
ESTETROL WITH DROSPIRENONE Pack containing 24 tablets estetrol 14.2 mg with drospirenone 3 mg and 4 inert tablets Nextstellis® MAYNE PHARMA INTERNATIONAL PTY LTD (New PBS listing)	Contraception	To request a General Schedule unrestricted listing.

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FARICIMAB Solution for intravitreal injection 21 mg in 0.175 mL (120 mg per mL) pre-filled syringe Vabysmo® ROCHE PRODUCTS PTY LTD (New PBS listing)	Macular oedema secondary to retinal vein occlusion (RVO)	To request a General Schedule Authority Required (Written) listing for the initial treatment and an Authority Required (STREAMLINED) listing for the continuing treatment of a new form for macular oedema secondary to RVO.
FEZOLINETANT Tablet 45 mg Veoza® ASTELLAS PHARMA AUSTRALIA PTY LTD (New PBS listing)	Moderate to severe menopause-related vasomotor symptoms (VMS)	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of moderate to severe menopause-related VMS.
FUTIBATINIB Tablet 4 mg Lytgobi® TAIHO PHARMA OCEANIA PTY LTD (New PBS listing)	Bile duct cancer (cholangiocarcinoma)	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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GEMCITABINE Solution for injection 1 g (as hydrochloride) in 25 mL Solution for injection 2 g (as hydrochloride) in 50 mL Gemcitabine Sandoz® SANDOZ PTY LTD (New PBS listing)	Various cancers	To request Section 100 (Efficient Funding of Chemotherapy Program) Unrestricted Benefit listings of new forms of gemcitabine.
INFLIXIMAB Solution for injection 120 mg in 1 mL pre-filled pen Solution for injection 120 mg in 1 mL pre-filled syringe Remsima® SC CELLTRION HEALTHCARE AUSTRALIA PTY LTD (Change to existing listing)	Severe active rheumatoid arthritis Ankylosing spondylitis Severe psoriatic arthritis Severe chronic plaque psoriasis Severe Crohn disease, Complex refractory fistulising Crohn Disease Moderate to severe ulcerative colitis	To request an amendment to the restriction level from Authority Required (Telephone/Online) to Authority Required (STREAMLINED) for the continuing treatment of the currently listed indications of Remsima® SC.

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INFLIXIMAB Powder for I.V. infusion 100 mg Ixifi® PFIZER AUSTRALIA PTY LTD (New PBS listing)	Severe active rheumatoid arthritis Ankylosing spondylitis Severe psoriatic arthritis Severe chronic plaque psoriasis Severe Crohn disease, Complex refractory fistulising Crohn Disease Moderate to severe ulcerative colitis	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.
IVACAFTOR Sachet containing granules 13.4 mg Kalydeco® VERTEX PHARMACEUTICALS (AUSTRALIA) PTY LTD (New PBS listing)	Cystic fibrosis (CF)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of CF patients aged 1 to 4 months who have a gating mutation or at least one mutation in the CF transmembrane conductance regulator gene.
LUMASIRAN Solution for subcutaneous injection 94.5 mg in 0.5 mL Oxlumo® MEDISON PHARMA AUSTRALIA PTY LTD (New PBS listing)	Primary hyperoxaluria type 1	To request a General Schedule Authority Required (STREAMLINED) listing for primary hyperoxaluria type 1.

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MIDOSTAURIN Capsule 25 mg Rydapt® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LTD (Change to existing listing)	Advanced systemic mastocytosis	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of adult patients with advanced systemic mastocytosis.
MOGAMULIZUMAB Solution concentrate for I.V. infusion 20 mg in 5 mL Poteligeo® KYOWA KIRIN AUSTRALIA PTY LTD (New PBS listing)	Cutaneous T-cell lymphoma (CTCL)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Written) listing for the treatment of relapsed or refractory CTCL (mycosis fungoides or Sezary syndrome) who have previously been treated with at least one prior systemic therapy.
NATALIZUMAB Solution concentrate for I.V. infusion 300 mg in 15 mL Tyruko® SANDOZ PTY LTD (New PBS listing)	Relapsing-remitting multiple sclerosis (RRMS)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing of a natalizumab biosimilar for the treatment of RRMS under the same conditions as its reference biologic.

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NIRSEVIMAB Solution for injection 50 mg in 0.5 mL pre-filled syringe Solution for injection 100 mg in 1 mL pre-filled syringe Beyfortus® SANOFI-AVENTIS AUSTRALIA PTY LTD (New NIP listing) TO BE CONSIDERED AT THE MAY 2025 PBAC MEETING	Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)	Resubmission to request a National Immunisation Program listing for the prevention of RSV lower respiratory tract disease in neonates and infants born during or entering their first RSV season; and children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.
ODEVIXIBAT Capsule 200 micrograms Capsule 400 micrograms Capsule 600 micrograms Capsule 1200 micrograms Bylvay® IPSEN PTY LTD (New PBS listing)	Progressive familial intrahepatic cholestasis (PFIC)	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of PFIC.

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OMALIZUMAB Injection 75 mg in 0.5 mL single dose pre-filled syringe Injection 150 mg in 1 mL single dose pre-filled syringe Omlyclo® CELLTRION HEALTHCARE AUSTRALIA PTY LTD (New PBS listing)	Uncontrolled severe asthma Uncontrolled severe allergic asthma Severe chronic spontaneous urticaria	To request Section 100 (Highly Specialised Drugs Program) Authority Required listings of an omalizumab biosimilar for the treatment of uncontrolled severe asthma, uncontrolled severe allergic asthma, and severe chronic spontaneous urticaria, under the same conditions as its reference biologic.

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OMALIZUMAB Injection 75 mg in 0.5 mL single dose pre-filled syringe Injection 150 mg in 1 mL single dose pre-filled syringe Injection 300 mg in 2 mL single dose pre-filled syringe Injection 75 mg in 0.5 mL single dose pre-filled pen Injection 150 mg in 1 mL single dose pre-filled pen Injection 300 mg in 2 mL single dose pre-filled pen Xolair® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED (New PBS listing)	Uncontrolled severe asthma Uncontrolled severe allergic asthma Severe chronic spontaneous urticaria	To request Section 100 (Highly Specialised Drugs Program) Authority Required listings of a new strength and new forms of omalizumab for the treatment of uncontrolled severe asthma, uncontrolled severe allergic asthma, and severe chronic spontaneous urticaria.
OMAVELOXOLONE Capsule 50 mg Skyclarys® BIOGEN AUSTRALIA PTY LTD (New PBS listing)	Friedreich’s ataxia	To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of Friedreich’s ataxia in adults and adolescents aged 16 years and older.

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PALOPEGTERIPARATIDE 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 Yorvipath® SPECIALISED THERAPEUTICS PHARMA PTY LTD (New PBS listing)	Chronic hypoparathyroidism	To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of chronic hypoparathyroidism.
PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® MERCK SHARP & DOHME (AUSTRALIA) PTY LTD (Change to existing listing)	Cervical cancer	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of high risk, locally advanced cervical cancer.

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PERTUZUMAB Solution for I.V. infusion 420 mg in 14 mL Perjeta® ROCHE PRODUCTS PTY LTD (Change to existing listing)	Human epidermal growth factor receptor 2-positive (HER2+) locally advanced, inflammatory or early stage breast cancer	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (Telephone/Online) listing, in combination with trastuzumab and chemotherapy, for the neoadjuvant treatment of HER2+ locally advanced, inflammatory or early stage breast cancer.
POLATUZUMAB VEDOTIN Powder for I.V. infusion 30 mg Powder for I.V. infusion 140 mg Polivy® ROCHE PRODUCTS PTY LTD (New PBS listing)	Diffuse large B-cell lymphoma (DLBCL)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing, in combination with rituximab, cyclophosphamide, doxorubicin and prednisone, for the treatment of previously untreated DLBCL.

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RAVULIZUMAB Solution concentrate for I.V. infusion 300 mg in 3 mL Solution concentrate for I.V. infusion 1,100 mg in 11 mL Ultomiris® ALEXION PHARMACEUTICALS AUSTRALIASIA PTY LTD (Change to existing listing)	Generalised myasthenia gravis (gMG)	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of adult patients with gMG who are anti-acetylcholine receptor antibody positive.
ROZANOLIXIZUMAB Solution for subcutaneous infusion 280 mg in 2 mL (140 mg per mL) Rystiggo® UCB AUSTRALIA PTY LTD (New PBS listing)	Generalised myasthenia gravis (gMG)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of adult patients with gMG who are anti-acetylcholine receptor antibody positive.

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RUXOLITINIB Tablet 5 mg Tablet 10 mg Tablet 15 mg Tablet 20 mg Jakavi® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LTD (Change to existing listing)	Polycythemia vera (PV)	Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of adult patients with PV who are resistant to or intolerant of hydroxycarbamide (hydroxyurea).
SACITUZUMAB GOVITECAN Powder for injection 180 mg Trodelvy® GILEAD SCIENCES PTY LIMITED (Change to existing listing)	Breast cancer	To request a definition for human epidermal growth factor receptor 2 (HER2) status be added to the clinical criteria for the initial treatment of unresectable locally advanced or metastatic triple-negative breast cancer.

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SOTATERCEPT Powder for subcutaneous injection 45 mg (50 mg per mL) Powder for subcutaneous injection 60 mg (50 mg per mL) Winrevair® MERCK SHARP & DOHME (AUSTRALIA) PTY LTD (New PBS listing)	Pulmonary arterial hypertension (PAH)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Telephone/Online) listing as add on therapy for the treatment of Group 1 PAH.
TARLATAMAB Powder for injection 10 mg Imdelltra® AMGEN AUSTRALIA PTY LTD (New PBS listing) TO BE CONSIDERED AT A FUTURE PBAC MEETING	Small cell lung cancer	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the third-line plus treatment of extensive-stage small cell lung cancer.

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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.)
TEPROTUMUMAB Powder for I.V. infusion 500 mg Tepezza® AMGEN AUSTRALIA PTY LTD (New PBS listing)	Thyroid eye disease (TED)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of active, moderate-to-severe TED.
TORIPALIMAB Solution concentrate for I.V. infusion 240 mg in 6 mL (40 mg per mL) Zytorvi® DR REDDY'S LABORATORIES AUSTRALIA PTY LTD (New PBS listing)	Nasopharyngeal carcinoma	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of recurrent or metastatic nasopharyngeal carcinoma.

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USTEKINUMAB Injection 45 mg in 0.5 mL single use pre-filled syringe Injection 90 mg in 1 mL single use pre-filled syringe Solution concentrate for I.V. infusion 130 mg in 26 mL (5 mg per mL) Epyztek® SAMSUNG BIOEPIS AU PTY LTD (New PBS listing)	Severe chronic plaque psoriasis (CPP) Severe psoriatic arthritis (PsA) Severe Crohn disease (CD) Complex refractory fistulising CD (fCD)	To request General Schedule and Section 100 (Highly Specialised Drugs Program) listings of an ustekinumab biosimilar for the treatment of CPP, PsA, CD, and fCD.
ZILUCOPLAN Solution for injection 16.6 mg in 0.416 mL (as tetrasodium) pre-filled syringe Solution for injection 23 mg in 0.574 mL (as tetrasodium) pre-filled syringe Solution for injection 32.4 mg in 0.810 mL (as tetrasodium) pre-filled syringe Zilbrysq® UCB AUSTRALIA PTY LTD (New PBS listing)	Generalised myasthenia gravis (gMG)	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for initial treatment and a General Schedule Authority Required (Written) listing for continuing treatment of gMG.

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ZOLBETUXIMAB Powder for I.V. infusion 100 mg (20 mg per mL) Vyloy® ASTELLAS PHARMA AUSTRALIA PTY LTD (New PBS listing)	Gastric or gastroesophageal junction (G/GOJ) cancer	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the first-line treatment of locally advanced unresectable or metastatic epidermal growth factor receptor 2-negative G/GOJ adenocarcinoma.

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

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FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL 100mcg/62.5mcg/25mcg 200mcg/62.5mcg/25mcg Trelegy Ellipta® GLAXOSMITHKLINE AUSTRALIA PTY LTD (Sub-committee report DUSC analysis) TO BE CONSIDERED AT THE MAY 2025 PBAC MEETING	Severe Asthma	To assess the utilisation of PBS listed fluticasone furoate + umeclidinium + vilanteroal (Trelegy Ellipta®) and single inhaler triple therapies for the treatment of severe asthma.
MEDICINES FOR GASTROINTESTINAL STROMAL TUMOUR All brands and strengths Various sponsors (Sub-committee report DUSC Analysis) TO BE CONSIDERED AT THE MAY 2025 PBAC MEETING	Gastrointestinal Stromal Tumour	To assess the utilisation of PBS listed medicines for the treatment of gastrointestinal stromal tumour.

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ZANUBRUTINIB Capsule 80 mg Brukinsa® BEIGENE AUS PTY LTD (Sub-committee report DUSC analysis) TO BE CONSIDERED AT THE MAY 2025 PBAC MEETING	Waldenström Macroglobulinaemia	To assess the utilisation of PBS listed zanubrutinb for the treatment of Waldenström Macroglobulinaemia.
ALIROCUMAB Injection 300 mg in 2 mL single dose autoinjector Praluent® SANOFI-AVENTIS AUSTRALIA PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Familial heterozygous hypercholesterolaemia Non-familial hypercholesterolaemia	To request the PBAC review its March 2023 recommendation that has not yet been accepted by the applicant.

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BEVACIZUMAB Solution for I.V. infusion 100 mg in 4 mL Solution for I.V. infusion 400 mg in 16 mL Zirabev® PFIZER AUSTRALIA PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Various cancers	To request the PBAC review its July 2020 recommendation that has not yet been accepted by the applicant.
IXEKIZUMAB Injection 80 mg in 1 mL single dose pre-filled pen Taltz® ELI LILLY AUSTRALIA PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Non-radiographic axial spondyloarthritis	To request the PBAC review its November 2021 recommendation that has not yet been accepted by the applicant.

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SECUKINUMAB Injection 75 mg in 0.5 mL pre-filled syringe Injection 150 mg in 1 mL pre-filled pen Injection 300 mg in 2 mL pre-filled syringe Injection 300 mg in 2 mL pre-filled pen Cosentyx® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Paediatric psoriasis	To request the PBAC review its November 2021 recommendation that has not yet been accepted by the applicant.
Review of PBS items for nurse practitioner and endorsed midwife prescribing Various forms and strengths Various brands Various sponsors (Other matters)	Various	To request the PBAC consider a tranche of PBS-listed medicines which do not include nurse practitioners and endorsed midwives as authorised prescribers but may be suitable for prescribing by these health professionals.

Version 6

Items added or amended

1. IVACAFTOR (Kalydeco®) – Form(s) amended
2. TARLATAMAB (Imdelltra®) – To be considered at a future PBAC Meeting

Items added or amended previously

3. ALIROCUMAB (Praluent®) – Review of positive PBAC recommendations not accepted by applicants – Added
4. AMIVANTAMAB (Rybrevant®), LAZERTINIB (Lazcluze®) – Drug name, form, and submission purpose amended
5. BEVACIZUMAB (Zirabev®) – Review of positive PBAC recommendations not accepted by applicants – Added

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6. CIPAGLUCOSIDASE ALFA (Pombiliti®), MIGLUSTAT (Opfolda®) – Drug name amended
7. DABRAFENIB (Tafinlar®), TRAMETINIB (Mekinist®) – Drug name amended
8. EFLORNITHINE (Ifinwil®) – Purpose of submission amended
9. ELEXACAFTOR WITH TEZACAFTOR AND WITH IVACAFTOR, AND IVACAFTOR (Trikafta®) – Submission purpose amended
10. ELEXACAFTOR WITH TEZACAFTOR AND WITH IVACAFTOR, AND IVACAFTOR (Trikafta®) – Removed
11. ELRANATAMAB (Elrexfio®) – Purpose of submission amended
12. FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL (Trelegy Ellipta®) – To be considered at the May 2025 PBAC meeting
13. IXEKIZUMAB (Taltz®) – Review of positive PBAC recommendations not accepted by applicants – Added
14. MEDICINES FOR GASTROINTESTINAL STROMAL TUMOUR (All brands) – To be considered at the May 2025 PBAC meeting
15. NIRSEVIMAB (Beyfortus®) – Submission purpose amended, to be considered at the May 2025 PBAC meeting
16. Review of PBS items for nurse practitioner and endorsed midwife prescribing (Various brands) – Added
17. SECUKINUMAB (Cosentyx®) – Review of positive PBAC recommendations not accepted by applicants – Added
18. ZANUBRUTINIB (Brukinsa®) – To be considered at the May 2025 PBAC meeting