PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
July 2024 PBAC MEETING

Closing date for consumer comments 29 May 2024

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.

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 drug 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.)
ADALIMUMAB Injection 20 mg in 0.2 mL pre-filled syringe Injection 40 mg in 0.4 mL pre-filled syringe Injection 40 mg in 0.4 mL pre-filled pen Injection 80 mg 0.8 mL pre-filled syringe Injection 80 mg in 0.8 mL pre-filled pen Hyrimoz® SANDOZ PTY LTD (New PBS listing)	Severe Crohn disease (CD) Moderate to severe ulcerative colitis (UC) Severe active juvenile idiopathic arthritis (JIA) Complex refractory fistulising Crohn disease (CD) Severe active rheumatoid arthritis (RA) Severe psoriatic arthritis (PsA) Ankylosing spondylitis (AS) Severe chronic plaque psoriasis (CPP) Moderate to severe hidradenitis suppurativa (HS)	To request General Schedule and Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listings for initial treatment and Authority Required (STREAMLINED) listings for subsequent continuing treatment of new forms of an existing biosimilar under the same conditions as the currently listed forms and strengths as its reference biologic.

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ADRENALINE (EPINEPHRINE) I.M. injection 150 micrograms in 0.15 mL (as acid tartrate) single dose syringe auto injector I.M. injection 300 micrograms in 0.3 mL (as acid tartrate) single dose syringe auto injector Jext® Jnr Jext® HEALTH TECHNOLOGY ANALYSTS PTY LIMITED (New PBS listing)	Acute allergic reaction with anaphylaxis	To request a General Schedule Authority Required (Telephone/Online) listing of a new form for the treatment of acute allergic reaction with anaphylaxis.
APALUTAMIDE Tablet 240 mg Erlyand® JANSSEN-CILAG PTY LTD (New PBS listing)	Non-metastatic castration-resistant carcinoma of the prostate Metastatic castration-sensitive carcinoma of the prostate	To request a General Schedule Authority Required (Telephone/Online) listing of a new strength for the treatment of non-metastatic castration-resistant and metastatic castration-sensitive carcinoma of the prostate.

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ARIPIPRAZOLE I.M. injection (modified release) 720 mg in 2.4 mL pre-filled syringe I.M. injection (modified release) 960 mg in 3.2 mL pre-filled syringe Abilify Asimtufii® LUNDBECK AUSTRALIA PTY LTD (New PBS listing) TO BE CONSIDERED AT A FUTURE PBAC MEETING	Schizophrenia	To request a General Schedule Authority Required (STREAMLINED) listing of new forms for the maintenance treatment of schizophrenia.
BELZUTIFAN Tablet 40 mg Welireg® MERCK SHARP & DOHME (AUSTRALIA) PTY LIMITED (New PBS listing)	Von Hippel-Lindau (VHL) disease	To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of patients with VHL disease who require therapy for associated renal cell carcinoma, central nervous system haemangioblastomas, or pancreatic neuroendocrine tumours, not requiring immediate surgery.

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BLINATUMOMAB Powder for I.V. infusion 38.5 micrograms Blincyto® AMGEN AUSTRALIA PTY LIMITED (Change to existing listing)	Measurable residual disease (MRD)-negative B-cell precursor acute lymphoblastic leukaemia (B-ALL)	To request a Section 100 (Efficient Funding of Chemotherapy) listing for the treatment of newly diagnosed B-ALL in patients who are MRD-negative after initial induction chemotherapy.
DIENOGEST Tablet 2 mg Visanne® BAYER AUSTRALIA LTD (New PBS listing)	Endometriosis	To request a General Schedule Restricted Benefit listing for the treatment of endometriosis.

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DROSPIRENONE WITH ETHINYLESTRADIOL Pack containing 24 tablets 3 mg drospirenone with 20 micrograms ethinylestradiol (as betadex clathrate) and 4 inert tablets Yaz® Pack containing 21 tablets 3 mg drospirenone with 30 micrograms ethinylestradiol and 7 inert tablets Yasmin® BAYER AUSTRALIA LTD (New PBS listing)	Oral contraceptive Moderate acne vulgaris in women who seek oral contraception Premenstrual dysphoric disorder in women who have chosen oral contraceptives as their method of birth control	To request a General Schedule unrestricted listing.

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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)	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 therapies.
ESKETAMINE Nasal spray solution 28 mg in 0.2 mL (2 actuations) Spravato® JANSSEN-CILAG PTY LTD (New PBS listing)	Treatment-resistant depression	Resubmission to request a Section 100 (Highly Specialised Drug Program) Authority Required (Telephone/Online) listing for the treatment of treatment-resistant depression.

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ESTRADIOL Transdermal gel 500 micrograms (as hemihydrate) in 0.5 g sachet Sandrena® ORION PHARMA (AUS) PTY LIMITED (New PBS listing)	Climacteric symptoms after natural or surgical menopause	To request a General Schedule unrestricted listing.
FARICIMAB Solution for intravitreal injection 28.8 mg in 0.24 mL (120 mg per mL) Vabysmo® ROCHE PRODUCTS PTY LTD (Change to existing listing)	Retinal vein occlusion (RVO)	To request a General Schedule Authority Required (Telephone/Online) listing for initial treatment and an Authority Required (STREAMLINED) listing for continuing treatment of RVO.

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FRUQUINTINIB Capsule 1 mg Capsule 5 mg Fruzaqla® TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD. (New PBS listing) TO BE CONSIDERED AT A FUTURE PBAC MEETING	Metastatic colorectal cancer (mCRC)	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of patients with mCRC who have been previously treated with or who are not considered candidates for available therapies.
IPTACOPAN Capsule 200 mg Fabhalta® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED (New PBS listing)	Paroxysmal nocturnal hemoglobinuria (PNH)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of adults with PNH who have inadequate clinical response to C5 inhibitor treatment.

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IVOSIDENIB Tablet 250 mg Tibsovo® SERVIER LABORATORIES (AUST.) PTY. LTD. (New PBS listing)	Bile duct cancer (cholangiocarcinoma)	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma who have previously progressed on chemotherapy and have a confirmed *IDH1* mutation.
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 Somatuline® Autogel IPSEN PTY LTD (Change to existing listing)	Acromegaly Functional Carcinoid Tumour Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)	To request an amendment to the clinical criteria of the Section 100 (Highly Specialised Drug Program) Authority Required (STREAMLINED) listings for the treatment of acromegaly, functional carcinoid tumour, and non-functional GEP-NET.

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LECANEMAB Solution concentrate for I.V. infusion 200 mg in 2 mL (100 mg per mL) Solution concentrate for I.V. infusion 500 mg in 5 mL (100 mg per mL) Leqembi® EISAI AUSTRALIA PTY LTD (New PBS listing) WITHDRAWN	Early Alzheimer disease (EAD)	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of EAD, comprising mild cognitive impairment due to Alzheimer disease (AD), prodromal AD, or mild AD dementia.
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 (New PBS listing)	Advanced Parkinson disease	Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of advanced idiopathic Parkinson disease with severe motor fluctuations despite optimised alternative pharmacological treatment.

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LINZAGOLIX Tablet 100 mg (as choline) Tablet 200 mg (as choline) Yselty® THERAMEX AUSTRALIA PTY LTD (New PBS listing)	Moderate to severe symptomatic uterine fibroids	To request General Schedule Authority Required (Telephone/Online) for initiation and Authority Required (STREAMLINED) continuing listings for the treatment of moderate to severe symptomatic uterine fibroids.
METHOTREXATE Tablet 2.5 mg (as sodium) Tablet 10 mg (as sodium) Methoblastin® PFIZER AUSTRALIA PTY LTD (New PBS listing)	Chemotherapy and inflammatory conditions	To request a General Schedule unrestricted listing of new forms and to request listing of a new pack size.
MILK POWDER -- SYNTHETIC Low calcium oral powder 400 g (Locasol) Locasol® NUTRICIA AUSTRALIA PTY LIMITED (Change to existing listing)	Hypercalcaemia	To request Locasol with new formulation continue to be listed on the PBS under the existing conditions.

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MORPHINE Tablet containing morphine sulfate pentahydrate 30 mg Anamorph® ARROW PHARMA PTY LTD (New PBS listing)	Severe pain, cancer pain, severe disabling pain	To request a General Schedule Restricted Benefit listing for the treatment of severe pain and cancer pain, and a Palliative Care Schedule Authority Required (Telephone/Online) listing for the treatment of severe disabling pain.
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 PBS listing)	Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)	To request a General Schedule Restricted Benefit listing for 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.

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NIVOLUMAB Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL Opdivo® IPILIMUMAB Injection concentrate for I.V. infusion 50 mg in 10 mL Yervoy® BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD (Change to existing listing)	Unresectable malignant mesothelioma	To request the PBAC consider the previously estimated utilisation for nivolumab and ipilimumab for the treatment of unresectable malignant mesothelioma.

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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)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of PFIC.
OLAPARIB Tablet 100 mg Tablet 150 mg Lynparza® ASTRAZENECA PTY LTD (Change to existing listing)	Human epidermal growth factor 2 (HER2) negative metastatic breast cancer with a confirmed *BRCA1* or *BRCA2* mutation	To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of HER2-negative metastatic breast cancer for patients with a confirmed *BRCA1* or *BRCA2* mutation.

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PRASUGREL Tablet 5 mg Tablet 10 mg Prasugrel SCP GENERIC HEALTH PTY LTD (New PBS listing)	Acute coronary syndrome	Resubmission to request a General Schedule Authority Required (STREAMLINED) listing, in combination with aspirin, for the treatment of acute coronary syndrome (myocardial infarction or unstable angina) managed by percutaneous coronary intervention.
PROGESTERONE Capsule 300 mg Utrogestan® BESINS HEALTHCARE AUSTRALIA PTY LTD (New PBS listing)	Luteal phase support	To request a Section 100 (In Vitro Fertilisation Program) Authority Required (STREAMLINED) listing of a new strength for luteal phase support as part of an assisted reproductive technology treatment cycle.
PROPYLENE GLYCOL Eye drops 60 micrograms per mL, 10 mL Systane Balance® ALCON LABORATORIES (AUSTRALIA) PTY LTD (New PBS listing)	Severe dry eye syndrome	To request a General Schedule Restricted Benefit listing for the treatment of severe dry eye syndrome.

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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 AUSTRALASIA 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.
RESPIRATORY SYNCYTIAL VIRUS VACCINE Powder and suspension for injection (0.5 mL) Arexvy® GLAXOSMITHKLINE AUSTRALIA PTY LTD (New NIP listing)	Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)	To request a National Immunisation Program listing for the prevention of RSV in patients aged 60 years and over.

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RISDIPLAM Powder for oral solution 750 micrograms per mL, 80 mL Evrysdi® ROCHE PRODUCTS PTY LTD (Change to existing listing)	Spinal muscular atrophy (SMA)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of patients with confirmed genetic diagnosis of SMA (*SMA1* deletion or mutation) who have a *SMN2* gene copy number of 3.
SELPERCATINIB Capsule 40 mg Capsule 80 mg Retevmo® ELI LILLY AUSTRALIA PTY LTD (New PBS listing)	Non-small cell lung cancer (NSCLC)	Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of advanced or metastatic, rearranged during transfection (RET) fusion-positive NSCLC.

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TALAZOPARIB Capsule 0.1 mg Capsule 0.25 mg Capsule 0.35 mg Capsule 0.5 mg Talzenna® PFIZER AUSTRALIA PTY LTD (New PBS listing)	Prostate cancer (PC)	Resubmission to request a General Schedule Authority Required (STREAMLINED) listing, in combination with enzalutamide, for the treatment of metastatic castration resistant PC in patients with a *BRCA1* or *BRCA2* mutation who have not received prior treatment with a novel hormonal agent.
VEDOLIZUMAB Powder for injection 300 mg Entyvio® TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD. (Change to existing listing)	Chronic pouchitis	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for initial treatment and an Authority Required (Telephone/Online) listing for continuing treatment of chronic pouchitis.

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ZANUBRUTINIB Capsule 80 mg Brukinsa® BEIGENE AUS PTY LTD (Change to existing listing)	Waldenström macroglobulinaemia	To request the PBAC consider the previously estimated utilisation of zanubrutinib for the treatment of Waldenström macroglobulinaemia.
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 PROPRIETARY LIMITED (New PBS listing)	Generalised myasthenia gravis (gMG)	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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BRENTUXIMAB VEDOTIN Powder for I.V. infusion 50 mg Adcetris® TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD (Sub-committee report DUSC Analysis)	Cutaneous and peripheral T-cell lymphoma	To review the written authority requirement for brentuximab vedotin for cutaneous and peripheral T-cell lymphoma.

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GALCANEZUMAB Injection 120 mg in 1 mL pre-filled pen Emgality® ELI LILLY AUSTRALIA PTY LTD FREMANEZUMAB Solution for injection 225 mg in 1.5 mL single dose pre-filled pen Solution for injection 225 mg in 1.5 mL single dose pre-filled syringe Ajovy® TEVA PHARMA AUSTRALIA PTY LTD (Sub-committee report DUSC Analysis)	Chronic migraine	To assess the utilisation of PBS listed galcanezumab and fremanezumab for the treatment of chronic migraine.

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SEMAGLUTIDE Solution for injection 2 mg in 1.5 mL pre-filled pen Solution for injection 4 mg in 3 mL pre-filled pen Ozempic® NOVO NORDISK PHARMACEUTICALS PTY. LIMITED (Sub-committee report DUSC Analysis)	Type 2 diabetes mellitus (T2DM)	To assess the utilisation of PBS listed semaglutide and other glucagon-like peptide 1 (GLP-1) analogues for the treatment of T2DM.
AVELUMAB Solution concentrate for I.V. infusion 200 mg in 10 mL Bavencio® MERCK HEALTHCARE PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Stage IV clear cell variant renal cell carcinoma	-

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DULAGLUTIDE Injection 3 mg in 0.5 mL single dose pre-filled pen Injection 4.5 mg in 0.5 mL single dose pre-filled pen Trulicity® ELI LILLY AUSTRALIA PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Type 2 diabetes mellitus (T2DM)	-
HUMAN MENOPAUSAL GONADOTROPHIN Injection 600 I.U. in 1.92 mL pre-filled multi-dose pen Injection 1,200 I.U. in 1.92 mL pre-filled multi-dose pen Menopur® FERRING PHARMACEUTICALS PTY LIMITED (Review of positive PBAC recommendations not accepted by applicants)	Assisted reproductive technology	-

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IBRUTINIB Capsule 140 mg Imbruvica® JANSSEN-CILAG PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Chronic lymphocytic leukaemia (CLL) and small lymphocytic lymphoma (SLL) with evidence of one or more 17p chromosome deletions	-
PANCREATIC EXTRACT Capsule (containing enteric coated minimicrospheres) providing not less than 20,000 BP units of lipase activity Creon® VIATRIS PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Cystic fibrosis	-

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
July 2024 PBAC MEETING

Closing date for consumer comments 29 May 2024

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.)
PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® MERCK SHARP & DOHME (AUSTRALIA) PTY LIMITED (Review of positive PBAC recommendations not accepted by applicants)	Advanced or metastatic gastro-oesophageal cancers	-
PROGESTERONE Pessary 400 mg Cyclogest® GEDEON RICHTER AUSTRALIA PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Assisted reproductive technology	-

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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.)
TRIENTINE Tablet 150 mg (as tetrahydrochloride) Cuprior® ORPHALAN (Review of positive PBAC recommendations not accepted by applicants)	Wilson disease	-
USTEKINUMAB Injection 90 mg in 1 mL pre-filled syringe Stelara® JANSSEN-CILAG PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Crohn disease Severe chronic plaque psoriasis	-

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
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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.)
OCULAR LUBRICANTS FOR THE TREATMENT OF SEVERE DRY EYE SYNDROME All brands and strengths Various sponsors DEPARTMENT OF HEALTH AND AGED CARE (Other matters)	Severe dry eye syndrome	To provide the PBAC with the findings following a systematic literature review comparing the efficacy and safety of preservative-containing ocular lubricants versus preservative-free ocular lubricants in patients with severe dry eye syndrome.
OSTEOPOROSIS THERAPY RESTRICTIONS REVIEW ALENDRONATE RISEDRONATE ZOLEDRONIC ACID Various forms and strengths Various brands Various sponsors (Change to existing listing)	Osteoporosis	To consider the impact of potential broadening of restrictions for osteoporosis therapies. This matter was deferred at the September 2021 PBAC meeting.

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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.)
SODIUM-GLUCOSE COTRANSPORTER 2 (SGLT2) INHIBITORS FOR THE TREATMENT OF TYPE 2 DIABETES MELLITUS DAPAGLIFLOZIN SAXAGLIPTIN WITH DAPAGLIFLOZIN DAPAGLIFLOZIN WITH METFORMIN All forms and strengths Forxiga® Qtern® 5/10 Xigduo® XR ASTRAZENECA PTY LTD EMPAGLIFLOZIN EMPAGLIFOZIN WITH LINAGLIPTIN EMPAGLIFLOZIN WITH METFORMIN All forms and strengths Jardiance® Glyxambi® Jardiamet® BOEHRINGER INGELHEIM PTY LTD (Change to existing listing)	Type 2 diabetes mellitus (T2DM)	To request the PBAC reconsider its March 2022 recommendation and the estimated costs for SGLT2 inhibitors (dapagliflozin and empagliflozin) to be listed as add-on therapy to metformin for the treatment of T2DM patients with cardiovascular disease or high cardiovascular risk

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REVIEW OF ITEMS FOR NURSE PRACTITIONER AND ENDORSED MIDWIFE PRESCRIBING ON THE PHARMACEUTICAL BENEFITS SCHEME Various forms and strengths Various brands Various sponsors (Other matters)	Various medicines	To seek the PBAC's consideration of a list of medicines with a Shared Care Model (SCM) administrative note for nurse practitioner prescribing, and advice on whether the SCM note continues to be appropriate for specific listings.

Version 7
Items added or amended
1. LECANEMAB (Leqembi®) – Withdrawn

Items added or amended previously
2. ARIPIPRAZOLE (Abilify Asimtufii®) – To be considered at a future PBAC meeting
3. FRUQUINTINIB (Fruzaqla®) – To be considered at a future PBAC meeting
4. LECANEMAB (Leqembi®) - To be considered at a future PBAC meeting
5. MORPHINE (Anamorph®) – Added
6. RAVULIZUMAB (Ultomiris®) - Added
7. AVELUMAB (Bavencio®) – Sponsor amended
8. REVIEW OF ITEMS FOR NURSE PRACTITIONER AND ENDORSED MIDWIFE PRESCRIBING ON THE PHARMACEUTICAL BENEFITS SCHEME (Various brands) – Added
9. ADRENALINE (EPINEPHRINE) (Jext® Jnr; Jext®) – Sponsor amended
10. LEVODOPA WITH CARBIDOPA AND ENTACAPONE (Lecigon®) – Added
11. ODEVIXIBAT (Bylvay®) – Purpose of submission amended
12. PRASUGREL (Prasugrel SCP) – Added
13. TALAZOPARIB (Talzenna®) – Added
14. AVELUMAB (Bavencio®) – Review of positive PBAC recommendations not accepted by applicants – Added
15. DULAGLUTIDE (Trulicity®) - Review of positive PBAC recommendations not accepted by applicants – Added
16. HUMAN MENOPAUSAL GONADOTROPHIN (Menopur®) - Review of positive PBAC recommendations not accepted by applicants – Added
17. IBRUTINIB (Imbruvica®) - Review of positive PBAC recommendations not accepted by applicants – Added
18. PANCREATIC EXTRACT (Creon®) – Review of positive PBAC recommendations not accepted by applicants – Added

19. PEMBROLIZUMAB (Keytruda®) – Review of positive PBAC recommendations not accepted by applicants – Added
20. PROGESTERONE (Cyclogest®) – Review of positive PBAC recommendations not accepted by applicants – Added
21. TRIENTINE (Cuprior®) - Review of positive PBAC recommendations not accepted by applicants – Added
22. USTEKINUMAB (Stelara®) - Review of positive PBAC recommendations not accepted by applicants – Added
23. OCULAR LUBRICANTS FOR THE TREATMENT OF SEVERE DRY EYE SYNDROME (Various brands) – Added
24. OSTEOPOROSIS THERAPY RESTRICTIONS REVIEW (Various brands) – Added
25. SODIUM-GLUCOSE COTRANSPORTER 2 (SGLT2) INHIBITORS FOR THE TREATMENT OF TYPE 2 DIABETES MELLITUS (Various brands) – Added
26. FARICIMAB (Vabysmo®) – Form, submission type and purpose of submission amended
27. FRUQUINTINIB (Fruzaqla®) – Form amended