PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2023 PBAC MEETING

Closing date for consumer comments 20 September 2023

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

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.)
ABEMACICLIB Tablet 50 mg Tablet 100 mg Tablet 150 mg Verzenio® ELI LILLY AUSTRALIA PTY LTD (Change to existing listing)	Hormone receptor positive (HR+) human epidermal growth factor receptor 2 negative (HER2-) breast cancer	To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of HR+ HER2- lymph node positive, invasive, resected early breast cancer at high risk of disease recurrence.

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ADALIMUMAB Injection 40 mg in 0.4 mL pre-filled syringe Injection 40 mg in 0.4 mL pre-filled pen Hadlima® ORGANON PHARMA PTY LTD (New listing)	Severe Crohn disease Moderate to severe ulcerative colitis Severe active juvenile idiopathic arthritis Complex refractory fistulising Crohn disease Severe active rheumatoid arthritis Severe psoriatic arthritis Ankylosing spondylitis Severe chronic plaque psoriasis Moderate to severe hidradenitis suppurativa	To request a General Schedule Authority Required (Written) listing of HADLIMA® 40 mg in 0.4 mL pre-filled syringe and 40 mg in 0.4 mL pre-filled pen under the same circumstances as the PBS-listed reference biologic HUMIRA® for all indications for which HADLIMA® 40 mg in 0.8 mL pre-filled syringe and 40 mg in 0.8 mL pre-filled pen are currently listed on the PBS.
APREMILAST Tablet 30 mg Pack containing 4 tablets 10 mg, 4 tablets 20 mg and 19 tablets 30 mg Otezla® AMGEN AUSTRALIA PTY LIMITED (Change to existing listing)	Chronic plaque psoriasis (CPP)	To request a change in the General Schedule Authority Required (STREAMLINED) listing for the treatment of severe CPP to allow treatment initiation by additional medical practitioner types.

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BUDESONIDE + FORMOTEROL Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 60 doses Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses Bufomix Easyhaler® ORION PHARMA (AUS) PTY LIMITED (New listing)	Asthma Chronic obstructive pulmonary disease (COPD)	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of asthma and COPD on the basis of bioequivalence to SYMBICORT TURBUHALER®.
CABOZANTINIB Tablet 20 mg Tablet 40 mg Tablet 60 mg Cabometyx® IPSEN PTY LTD (Change to existing listing)	Differentiated thyroid cancer (DTC)	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of locally advanced or metastatic DTC in patients who have progressed during or after prior vascular endothelial growth factor-targeted therapy.

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CEMIPLIMAB Solution for I.V. infusion 350 mg in 7 mL Libtayo® SANOFI-AVENTIS AUSTRALIA PTY LTD (Change to existing listing)	Non-small cell lung cancer (NSCLC)	To request a Section 100 (Efficicent Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing to be used with platinum doublet chemotherapy as a first line treatment of adult patients with Stage IV (metastatic) NSCLC.
CHLORMETHINE HYDROCHLORIDE Gel 160 microgram per g, 60 g Ledaga® JUNIPER BIOLOGICS PTY LTD (New listing)	Mycosis fungoides-type cutaneous T-cell lymphoma (MF-type CTCL)	To request a General Schedule Authority Required (Telephone/Online) listing for the topical treatment of MF-type CTCL.
CLADRIBINE Tablet 10 mg Mavenclad® MERCK HEALTHCARE PTY LTD (Change to existing listing)	Relapsing-remitting multiple sclerosis (RRMS)	To request a revision to the equi-effective doses of cladribine versus fingolimod for the treatment of RRMS.

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DAUNORUBICIN WITH CYTARABINE Powder for I.V infusion containing daunorubicin 44 mg and cytarabine 100 mg Vyxeos® Jazz Pharmaceuticals ANZ Pty Ltd (New listing)	Acute myeloid leukaemia	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for the treatment of therapy-related acute myeloid leukaemia (t-AML) and acute myeloid leukaemia with myelodysplasia-related changes (AML-MRC).
DIFELIKEFALIN Solution for I.V. injection 50 micrograms in 1 mL vial Korsuva® VIFOR PHARMA PTY LIMITED (New listing)	Chronic kidney disease associated pruritus	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Telephone/Online) listing for the treatment of moderate-to-severe pruritus associated with chronic kidney disease.
DOSTARLIMAB Solution concentrate for I.V. infusion 500 mg in 10 mL Jemperli® GLAXOSMITHKLINE AUSTRALIA PTY LTD (New listing)	Endometrial cancer	To request a Section 100 (EFC) Authority Required (STREAMLINED) listing for use in combination with platinum-containing chemotherapy for the treatment of primary advanced or first recurrent endometrial cancer.

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DUPILUMAB Injection 200 mg in 1.14 mL single dose pre-filled syringe Injection 300 mg in 2 mL single dose pre-filled syringe Dupixent® SANOFI-AVENTIS AUSTRALIA PTY LTD UPADACITINIB Tablet 15 mg Tablet 30 mg Rinvoq® ABBVIE PTY LTD (Matters outstanding)	Severe atopic dermatitis (AD)	PBAC consideration of the cost-effectiveness of dupilumab and upadacitinib for severe AD.

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EDARAVONE Solution concentrate for injection 30 mg in 20 mL Radicava® TEVA PHARMA AUSTRALIA PTY LTD (New listing)	Amyotrophic lateral sclerosis (ALS)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Telephone/Online) listing for the treatment of ALS.
ELTROMBOPAG Tablet 25 mg Tablet 50 mg Revolade® HAEMATOLOGY SOCIETY OF AUSTRALIA AND NEW ZEALAND (Change to existing listing)	Aplastic anaemia (AA)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of severe AA.
EMPAGLIFLOZIN Tablet 10 mg Jardiance® BOEHRINGER INGELHEIM PTY LTD (Change to existing listing)	Chronic kidney disease	To request a General Schedule Authority Required (STREAMLINED) listing for chronic kidney disease.

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FLUTICASONE PROPIONATE + SALMETEROL Powder for oral inhalation in breath actuated device containing fluticasone propionate 250 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses Powder for oral inhalation in breath actuated device containing fluticasone propionate 500 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses Salflumix Easyhaler® ORION PHARMA (AUS) PTY LIMITED (New listing)	Asthma Chronic obstructive pulmonary disease (COPD)	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of asthma and COPD
ICOSAPENT ETHYL Capsule 1 g Vazkepa® SEQIRUS (AUSTRALIA) PTY LTD (New listing)	Atherosclerotic cardiovascular disease with elevated triglycerides	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of atherosclerotic cardiovascular disease with elevated triglycerides.

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IMATINIB, DASATINIB, NILOTINIB, PONATINIB, ASCIMINIB All brands and strengths Various sponsors (Other matters) To be considered at a future PBAC meeting	Chronic myeloid leukaemia (CML)	For the PBAC to consider updating the restriction wording for tyrosine kinase inhibitors (TKIs) in CML.
IVACAFTOR Sachet containing granules 25 mg Sachet containing granules 50 mg Sachet containing granules 75 mg Tablet 150 mg Kalydeco® VERTEX PHARMACEUTICALS (AUSTRALIA) PTY. LTD. (New listing)	Cystic fibrosis (CF) with the CF transmembrane conductance regulator (CFTR) gene mutation	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of (i) CF patients aged 4 to 12 months with a gating (Class III) CFTR gene mutation; (ii) CF patients aged 4 months or older with at least one CFTR gene mutation shown to be responsive to ivacaftor potentiation.

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LENACAPAVIR Tablet 300 mg Injection set containing 2 vials lenacapavir sodium solution for injection 463.5 mg in 1.5 mL and 2 disposable syringes Sunlenca® GILEAD SCIENCES PTY LIMITED (New listing)	Human immunodeficiency virus (HIV)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of multidrug resistant HIV.
LENALIDOMIDE Capsule 20 mg Lenalide® JUNO PHARMACEUTICALS PTY LTD (New listing)	Multiple myeloma (MM) Myelodysplastic syndromes (MDS) Mantle cell lymphoma (MCL)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Telephone/Online) listing of a new strength under the same conditions and for the same population as the currently listed strengths.

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MARIBAVIR Tablet 200 mg Livtencity® TAKEDA PHARMACEUTICALS AUSTRALIA PTY LTD (New listing)	Post-transplant cytomegalovirus (CMV)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for treatment of post-transplant CMV infection and disease that is refractory, resistant or intolerant to one or more prior therapies.
MAVACAMTEN Capsule 2.5 mg Capsule 5 mg Capsule 10 mg Capsule 15 mg Camzyos® BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD (New listing)	Hypertrophic cardiomyopathy	Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy.

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MEDROXYPROGESTERONE ACETATE Suspension for injection 150 mg in 1 mL pre-filled syringe Depo-Provera® PFIZER AUSTRALIA PTY LTD (New listing)	Unrestricted benefit	To request a General Schedule unrestricted listing for a pre-filled syringe that will replace the currently listed vial.
MENINGOCOCCAL VACCINE Injection 0.5 mL Menveo® GLAXOSMITHKLINE AUSTRALIA PTY LTD (New listing)	Prevention of invasive meningococcal diseases (IMDs)	To request a National Immunisation Program listing for adolescents for the prevention of IMDs caused by Neisseria meningitidis serogroups A, C, W-135 and Y

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MIDAZOLAM Oromucosal solution in pre-filled syringe 2.5 mg in 0.25 mL Oromucosal solution in pre-filled syringe 5 mg in 0.5 mL Oromucosal solution in pre-filled syringe 7.5 mg in 0.75 mL Oromucosal solution in pre-filled syringe 10 mg in 1 mL Zyamis® CLINECT PTY LTD (Other matters)	Generalised convulsive status epilepticus (GCSE)	To request consideration of revised financial estimates and risk share proposal for a General Schedule Authority required (Telephone/Online) listing for the treatment of GCSE.
MOLNUPIRAVIR Capsule 200 mg Lagevrio® MERCK SHARP & DOHME (AUSTRALIA) PRT LTD (Matters outstanding)	Mild to moderate SARS-CoV-2 infection	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of high risk patients with mild to moderate SARS-CoV-2 infection.

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NIRMATRELVIR AND RITONAVIR Pack containing 4 tablets nirmatrelvir 150 mg and 2 tablets ritonavir 100 mg, 5 Paxlovid® PFIZER AUSTRALIA PTY LTD (Change to existing listing)	SARS-CoV-2 infection	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of SARS-CoV-2 infection in people who are at increased risk of severe disease.
NIVOLUMAB Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL Opdivo® BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD (Change to existing listing)	Muscle invasive urothelial carcinoma (MIUC)	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for the adjuvant treatment of high-risk MIUC.

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OLAPARIB Tablet 100 mg Tablet 150 mg Lynparza® ASTRAZENECA PTY LTD (Change to existing listing)	Metastatic castration-resistant prostate cancer (mCRPC)	To request a General Schedule Authority Required (Telephone/Online) listing for the first line treatment of mCRPC in patients with a Class 4 or 5 Breast Cancer Gene 1 (BRCA1) or BRCA2 mutation who have not received prior treatment with a novel hormonal agent.
OLAPARIB Tablet 100 mg Tablet 150 mg Lynparza® ASTRAZENECA PTY LTD (Change to existing listing)	Human epidermal growth factor receptor 2 (HER2)-negative early breast cancer	To request a General Schedule Authority Required (Telephone/Online) listing for patients with HER2-negative high risk early breast cancer with a confirmed germline Breast Cancer Gene 1 (BRCA1) or BRCA2 mutation.
OSIMERTINIB Tablet 40 mg Tablet 80 mg Tagrisso® ASTRAZENECA PTY LTD (Change to existing listing)	Non-small cell lung cancer (NSCLC)	To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of Stage IB to IIIA epidermal growth factor receptor mutation positive NSCLC as adjuvant therapy after surgical resection.

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OXYBUTYNIN Transdermal patches 36 mg, 8 Oxytrol® THERAMEX AUSTRALIA PTY LTD (Change to existing listing)	Detrusor overactivity in patients unable to tolerate or unable to swallow oral oxybutynin	To request consideration of whether oxybutynin 3.9 mg transdermal patch satisfies the criteria to be classified an 'exempt item' as described by Section 84AH of the National Health Act 1953.
PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® MERCK SHARP & DOHME (AUSTRALIA) PTY LTD (Change to existing listing)	Squamous cell carcinoma (SCC)	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of metastatic or locally advanced cutaneous SCC that is not curative by surgery or radiation.
PNEUMOCOCCAL CONJUGATE VACCINE, 20-VALENT 0.5 mL pre-filled syringe Prevenar 20® PFIZER AUSTRALIA PTY LTD (New listing)	Prevention of pneumococcal disease	To request an NIP listing for paediatric populations.

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RISANKIZUMAB Injection 150 mg in 1 mL pre-filled syringe Injection 150 mg in 1 mL pre-filled pen Skyrizi® ABBVIE PTY LTD (Change to existing listing)	Chronic plaque psoriasis (CPP)	To request a General Schedule Authority Required (Written) listing for the treatment of severe CPP.
SACITUZUMAB GOVITECAN Powder for injection 180 mg Trodelvy® GILEAD SCIENCES PTY LIMITED (Change to existing listing)	Hormone receptor-positive (HR+) human epidermal growth factor receptor-2 negative (HER2-) advanced or metastatic breast cancer	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of adult patients with unresectable locally advanced or metastatic HR+, HER2- breast cancer, who have previously received at least two systemic therapies, one of which may have been in the neoadjuvant/adjuvant setting.

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SECUKINUMAB Solution for injection 300 mg in 2 mL pre-filled syringe Solution for injection 150 mg in 1 mL pre-filled syringe Solution for injection 150 mg in 1 mL pre-filled pen Solution for injection 300 mg in 2 mL pre-filled pen Cosentyx® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED (Change to existing listing)	Hidradenitis suppurativa (HS)	Resubmission to request a General Schedule Authority Required (Written) listing for the treatment of HS.

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SEMAGLUTIDE Injection 0.25 mg in 0.5 mL pre-filled single dose pen Injection 0.5 mg in 0.5 mL pre-filled single dose pen Injection 1.0 mg in 0.5 mg pre-filled single dose pen Injection 1.7 mg in 0.75 mL pre-filled single dose pen Injection 2.4 mg in 0.75 mL pre-filled single dose pen Wegovy® NOVO NORDISK PHARMACEUTICALS PTY. LIMITED (New listing)	Severe obesity	To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of severe obesity despite prior participation in an appropriate lifestyle-based weight management intervention.
TERIPARATIDE Injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled cartridge Teriparatide Lupin® GENERIC HEALTH PTY LTD (New listing)	Osteoporosis	To request a General Schedule Authority Required (STREAMLINED) listing under the same conditions as the currently listed brand TERROSA®.

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TERIPARATIDE Injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled pen Terrosa® GEDEON RICHTER AUSTRALIA PTY LTD (New listing)	Osteoporosis	To request a General Schedule Authority Required (STREAMLINED) listing for a pre-filled pen under the same conditions as the currently listed cartridge presentation.
TISLELIZUMAB Solution concentrate for injection 100 mg in 10 mL Tevimbra® BEIGENE AUS PTY LTD (New listing) To be considered at a future PBAC meeting	Non-small cell lung cancer (NSCLC)	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first-line treatment of patients with Stage IV (metastatic) NSCLC.

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TRASTUZUMAB DERUXTECAN Powder for I.V. infusion 100 mg Enhertu® ASTRAZENECA PTY LTD (New listing)	Human epidermal growth factor receptor 2 (HER2)-low breast cancer	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for the treatment of patients with HER2-low unresectable or metastatic breast cancer.
VARICELLA ZOSTER VIRUS RECOMBINANT VACCINE Injection 1 vial & adjuvant substance diluent 0.5 mL vial Shingrix® GLAXOSMITHKLINE AUSTRALIA PTY LTD (Matters outstanding)	Herpes zoster virus	To request consideration of the population that was deferred at the March 2023 PBAC meeting: broader population of immunocompromised individuals aged ≥ 18 years at increased risk of herpes zoster.

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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.)
ADALIMUMAB Injection 40 mg in 0.8 mL pre-filled pen Injection 40 mg in 0.8 mL pre-filled syringe Hulio® Alphapharm Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Severe Crohn disease Ulcerative colitis Juvenile idiopathic arthritis Complex refractory fistulising Crohn disease Rheumatoid arthritis Psoriatic arthritis Ankylosing spondylitis Chronic plaque psoriasis Hiradenitis suppurative	-
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)	Metastatic colorectal cancer Advanced, metastatic or recurrent non-squamous non-small lung cancer Relapsed or recurrent glioblastoma Epithelial ovarian, fallopian tube or primary peritoneal cancer Cervical cancer	-

Closing date for consumer comments 20 September 2023

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.)
ETANERCEPT Injection 50 mg in 1 mL single use pre-filled syringe Rymti® Alphapharm Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Rheumatoid arthritis Plaque psoriasis Ankylosing spondylitis Psoriatic arthritis Juvenile idiopathic arthritis Paediatric plaque psoriasis	-
INSULIN ASPART Injection (human analogue), cartridge 100 units per mL, 3 mL Injection (human analogue), pre-filled pen, 100 units per mL, 3 mL Truvelog® Truvelog Solostar® Sanofi-Aventis Australia Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Diabetes mellitus	-

Closing date for consumer comments 20 September 2023

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.)
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	-
MELATONIN Tablet 1 mg Tablet 5 mg Slenyto® Aspen Pharmacare Australia Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Smith-Magenis syndrome	-

Closing date for consumer comments 20 September 2023

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.)
RISANKIZUMAB Injection 150 mg in 1 mL pre-filled pen Injection 150 mg in 1 mL pre-filled syringe Skyrizi® AbbVie Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Severe chronic plaque psoriasis	-
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	

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2023 PBAC MEETING

Closing date for consumer comments 20 September 2023

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.)
OMALIZUMAB Injection 150 mg in 1 mL single dose pre-filled syringe Xolair® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED (Systematic literature review to supplement DUSC Analysis)	Chronic spontaneous urticaria (CSU)	To consider the findings of a systematic literature review of the most recent comparative clinical evidence for omalizumab and cyclosporin for the treatment of CSU, including the equi-effective dose, for comparison with the evidence previously considered by the PBAC.
APREMILAST Tablet 30 mg Pack containing 4 tablets 10 mg, 4 tablets 20 mg and 19 tablets 30 mg Otezla® AMGEN AUSTRALIA PTY LIMITED (Sub-committee report DUSC Analysis)	Severe chronic plaque psoriasis	To assess the utilisation of apremilast for the treatment of severe chronic plaque psoriasis

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2023 PBAC MEETING

Closing date for consumer comments 20 September 2023

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.)
DUPILUMAB Injection 200 mg in 1.14 mL single dose pre-filled syringe Injection 300 mg in 2 mL single dose pre-filled syringe Dupixent® SANOFI-AVENTIS AUSTRALIA PTY LTD (Sub-committee report DUSC Analysis)	Chronic severe atopic dermatitis	To assess the utilisation of dupilumab for the treatment of chronic severe atopic dermatitis

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2023 PBAC MEETING

Closing date for consumer comments 20 September 2023

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.)
LISDEXAMFETAMINE Capsule containing lisdexamfetamine dimesilate 20 mg Capsule containing lisdexamfetamine dimesilate 30 mg Capsule containing lisdexamfetamine dimesilate 40 mg Capsule containing lisdexamfetamine dimesilate 50 mg Capsule containing lisdexamfetamine dimesilate 60 mg Capsule containing lisdexamfetamine dimesilate 70 mg Vyvanse® TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD. (Sub-committee report DUSC Analysis)	Attention deficit hyperactivity disorder	To assess the utilisation of lisdexamfetamine for the treatment of attention deficit hyperactivity disorder

Closing date for consumer comments 20 September 2023

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.)
VENETOCLAX Pack containing 14 tablets venetoclax 10 mg and 7 tablets venetoclax 50 mg and 7 tablets venetoclax 100 mg and 14 tablets venetoclax 100 mg Tablet 100 mg Venclexta® ABBVIE PTY LTD (Sub-committee report DUSC Analysis)	Chronic lymphocytic leukaemia or small lymphocytic lymphoma	To assess the utilisation of venetoclax for the treatment of chronic lymphocytic leukaemia or small lymphocytic lymphoma

Version 6
Items added or amended

1. BUDESONIDE + FORMOTEROL (Bufomix Easyhaler®) – Drug form amended
2. CHLORMETHINE HYDROCHLORIDE (Ledaga®) – Drug form amended
3. FLUTICASONE PROPIONATE + SALMETEROL (Salflumix Easyhaler®) – Drug form amended
4. IVACAFTOR (Kalydeco®) – Drug form amended
5. LENACAPAVIR (Sunlenca®) – Drug form amended
6. OXYBUTYNIN (Oxytrol®) – Drug form amended

Items added or amended previously

7. ADALIMUMAB (Hulio®) – Review of positive PBAC recommendations not accepted by applicants – Added
8. BEVACIZUMAB (Zirabev®) – Review of positive PBAC recommendations not accepted by applicants - Added
9. DURVALUMAB (Infinzi®) – Review of positive PBAC recommendations not accepted by applicants - Added
10. ETANERCEPT (Rymti®) – Review of positive PBAC recommendations not accepted by applicants - Added
11. ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS (EAA Supplement™) – Review of positive PBAC recommendations not accepted by applicants - Added
12. INSULIN ASPART (Truvelog; Truvelog Solostar®) – Review of positive PBAC recommendations not accepted by applicants - Added
13. IXEKIZUMAB (Taltz®) – Review of positive PBAC recommendations not accepted by applicants - Added

14. MELATONIN (Slenyto®) – Review of positive PBAC recommendations not accepted by applicants - Added
15. RISANKIZUMAB (Skyriz®) – Review of positive PBAC recommendations not accepted by applicants - Added
16. SECUKINUMAB (Cosentyx®) – Review of positive PBAC recommendations not accepted by applicants - Added
17. DAUNORUBICIN AND CYTARABINE (Vyxeos®) – Added
18. SECUKINUMAB (Cosentyx®) – Added
19. MAVACAMTEN (Camzyos®) – Added
20. SACITUZUMAB GOVITECAN (Trodelvy®) – Added
21. DOSTARLIMAB (Jemperli®) – Purpose of submission amended
22. VARICELLA ZOSTER VIRUS RECOMBINANT VACCINE (Shingrix®) – Added
23. APREMILAST (Otezla®) – Drug form amended
24. DUPILUMAB (Dupixent®) and UPADACITINIB (Rinvoq®) – Added
25. OMALIZUMAB (Xolair®) – Systematic review to supplement DUSC Analysis – Drug form amended
26. APREMILAST (Otezla®) – Sub-committee DUSC Analysis – Drug form amended
27. DUPILIMAB (Dupixent®) - Sub-committee DUSC Analysis – Drug form amended
28. LISDEXAMFETAMINE (Vyvanse®) - Sub-committee DUSC Analysis – Drug form amended
29. VENETOCLAX (Venclexta®) - Sub-committee DUSC Analysis – Drug form amended
30. MIDAZOLAM (Zyamis®) – Added
31. IMATINIB, DASATINIB, NILOTINIB, PONATINIB, ASCIMINIB (all brands and strengths) – Added
32. MOLNUPIRAVIR (Lagevrio®) – Added
33. APREMILAST (Otezla®) – Drug form amended
34. TISLELIZUMAB (Tevimbra®) – To be considered at a future PBAC meeting
35. IMATINIB, DASATINIB, NILOTINIB, PONATINIB, ASCIMINIB (All brands and strengths) – To be considered at a future PBAC meeting
36. DURVALUMAB (Infinzi®) – Review of positive PBAC recommendations not accepted by applicants – Removed – sponsor has advised PBS listing is progressing
37. ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS (EAA Supplement™) – Review of positive PBAC recommendations not accepted by applicants – Removed – sponsor has advised PBS listing is progressing