

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
NOVEMBER 2021 PBAC MEETING**

Closing date for consumer comments 22 September 2021

The PBAC agenda primarily consists of applications relating to the new listing of a drug or vaccine on the PBS or the National Immunisation Program.

The PBAC agenda consists of the following:

- 1 Minutes of Previous Meeting**
- 2 Chairman'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.
- *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.

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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](#).

Submission type (new listing, change to listing)	Drug Name, form(s), strength(s) and Sponsor (Drug name, form, strength, Trade name®, Sponsor)	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.)
New PBS listing To be considered at a future PBAC meeting	ABROCITINIB Tablet 100 mg Tablet 200 mg Cibinqo® Pfizer Australia Pty Ltd	Atopic dermatitis	To request a General Schedule Authority Required listing for the treatment of severe atopic dermatitis.
Change to PBS listing	ACALABRUTINIB Capsule 100 mg Calquence® AstraZeneca Pty Ltd	Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)	Resubmission to request a General Schedule Authority Required listing for previously untreated CLL or SLL patients who are considered unsuitable for treatment with fludarabine-based chemoimmunotherapy, and unsuitable for venetoclax in combination with obinutuzumab, or who develop intolerance to venetoclax with obinutuzumab necessitating permanent treatment withdrawal.

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New PBS listing	ADALIMUMAB Injection 40 mg in 0.8 mL pre-filled pen Injection 40 mg in 0.8 mL pre-filled syringe Hulario® Alphapharm Pty Ltd	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 listing of adalimumab biosimilar under the same conditions as its reference biologic.
Change to listing	ADALIMUMAB Injection 80 mg in 0.8 mL pre-filled syringe Humira® AbbVie Pty Ltd	Severe Crohn disease; Moderate to severe ulcerative colitis.	To request General Schedule Authority Required listing of an additional strength of adalimumab as an induction dose for patients weighing less than 40 kg with Crohn disease or ulcerative colitis.
New PBS listing	AMIFAMPRIDINE Tablet 10 mg Ruzurgi® The Trustee For Orspec Pharma Unit Trust	Lambert-Eaton myasthenic syndrome	To request a General Schedule Authority Required (Written) listing for the treatment of Lambert-Eaton myasthenic syndrome in adults and children aged six years and above.

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New PBS listing	APALUTAMIDE Tablet 60 mg Eryand® Janssen-Cilag Pty Ltd	Prostate cancer	To request a General Schedule Authority Required listing for the treatment of patients with metastatic hormone-sensitive prostate cancer who have low-volume disease, or who have high-volume disease and are too frail for chemotherapy.
New PBS listing	APALUTAMIDE Tablet 60 mg Eryand® Janssen-Cilag Pty Ltd	Prostate cancer	Resubmission to request a General Schedule Authority Required listing for the treatment of castration-resistant prostate cancer with no distant metastases on conventional imaging.
New PBS listing	AVALGLUCOSIDASE ALFA Powder for injection 100 mg in 10 mL Nexvzyme® sanofi-aventis Australia Pty Ltd	Pompe disease	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of Pompe disease.

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New PBS listing	<p align="center"> BEVACIZUMAB Solution for I.V. infusion 100 mg in 4 mL Solution for I.V. infusion 400 mg in 16 mL Abevmy® Alphapharm Pty Ltd </p>	<p> Relapsed or recurrent glioblastoma; Advanced (unresectable) Barcelona Clinic Liver Cancer; Stage B or Stage C hepatocellular carcinoma; Stage IV (metastatic) non-small cell lung cancer (NSCLC); Advanced carcinoma of cervix; Advanced International Federation of Gynecology and Obstetrics (FIGO) Stage IIIB, IIIC or Stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer; Metastatic colorectal cancer. </p>	<p align="center"> To request listing of bevacizumab biosimilar under the same conditions as its reference biologic. </p>

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<p align="center">New PBS listing</p>	<p align="center"> BUPRENORPHINE Buvidal® Weekly: Injection (modified release) 8 mg in 0.16 mL pre-filled syringe Injection (modified release) 16 mg in 0.32 mL pre-filled syringe Injection (modified release) 24 mg in 0.48 mL pre-filled syringe Injection (modified release) 32 mg in 0.64 mL pre-filled syringe Buvidal® Monthly: Injection (modified release) 64 mg in 0.18 mL pre-filled syringe Injection (modified release) 96 mg in 0.27 mL pre-filled syringe Injection (modified release) 128 mg in 0.36 mL pre-filled syringe Injection (modified release) 160 mg in 0.45 mL pre-filled syringe (new strength) Buvidal® Weekly; Buvidal® Monthly Camurus Pty Ltd </p>	<p align="center">Opioid dependence</p>	<p align="center"> To request: a General Schedule listing in addition to the existing Section 100 (Opiate Dependence Treatment Program) listing under the same circumstances as the currently listed Buvidal®; listing an additional 160 mg strength of Buvidal® Monthly under the same circumstances as the currently listed Buvidal® Monthly; removing the requirement that a patient must be stabilised on sublingual buprenorphine or buprenorphine/naloxone prior to commencing treatment with Buvidal to align with recent regulatory updates by the TGA. </p>

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<p align="center">New PBS listing</p>	<p align="center"> CABOTEGRAVIR Tablet containing cabotegravir 30 mg Vocabria® CABOTEGRAVIR AND RILPIVIRINE Pack containing 1 injection of cabotegravir 600 mg in 3 mL and 1 injection of rilpivirine 900 mg in 3 mL Cabenuva® ViiV Healthcare Pty Ltd </p>	<p align="center">Human Immunodeficiency virus (HIV)</p>	<p align="center">Resubmission to request a Section 100 (Highly Specialised Drugs Program - Community Access) Authority Required (STREAMLINED) listing for the treatment of HIV infection in adults who are virologically suppressed.</p>
<p align="center">New PBS listing</p>	<p align="center"> CEMIPLIMAB Solution for I.V. infusion 350 mg in 7 mL Libtayo® sanofi-aventis Australia Pty Ltd </p>	<p align="center">Non-small cell lung cancer (NSCLC)</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of patients with stage IV NSCLC expressing PD-L1 with a tumour proportion score ≥50%.</p>
<p align="center"> New PBS listing To be considered at a future PBAC meeting </p>	<p align="center"> CEMIPLIMAB Solution for I.V. infusion 350 mg in 7 mL Libtayo® sanofi-aventis Australia Pty Ltd </p>	<p align="center">Squamous cell carcinoma (SCC)</p>	<p align="center">Resubmission to request Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of metastatic or locally advanced cutaneous SCC in patients who are not candidates for curative surgery or curative radiation.</p>

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Other business	CLADRIBINE Tablet 10 mg Mavenclad® Merck Healthcare Pty Ltd	Multiple sclerosis	To request the PBAC consider the equi-effective doses of cladribine and other PBS-listed therapies for the treatment of relapsing-remitting multiple sclerosis.
New PBS listing	DARATUMUMAB Solution for subcutaneous injection 1,800 mg in 15 mL vial Darzalex® SC Janssen-Cilag Pty Ltd	Amyloid light-chain (AL) amyloidosis	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing, for use in combination with cyclophosphamide, bortezomib and dexamethasone, for the treatment of patients with newly diagnosed AL amyloidosis.
Change to PBS listing	ECULIZUMAB Solution concentrate for I.V. infusion 300 mg in 30 mL Soliris® Alexion Pharmaceuticals Australasia Pty Ltd	Neuromyelitis optica spectrum disorder (NMOSD)	Resubmission to request an Authority Required (Written) listing for the treatment of patients with relapsing NMOSD who are anti-aquaporin-4 (AQP4) antibody positive.
Change to PBS listing	EMPAGLIFLOZIN Tablet 10 mg Jardiance® Boehringer Ingelheim Pty Ltd	Chronic heart failure	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of patients with chronic heart failure with reduced ejection fraction.

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Change to PBS listing	<p align="center">ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS</p> <p align="center">Sachets containing oral powder 12.5 g, 30</p> <p align="center">EAA Supplement</p> <p align="center">Vitaflo Australia Pty Limited</p>	<p align="center">Gyrate atrophy of the choroid and retina; Urea cycle disorders.</p>	<p align="center">To request EAA Supplement with new formulation and new pack size continue to be listed on the PBS; and to request a change of maximum quantity from four packs (200 sachets) to six packs (180 sachets).</p>
New PBS listing	<p align="center">ETANERCEPT</p> <p align="center">Injections 50 mg in 1 mL single use pre-filled syringes, 4</p> <p align="center">Rymti®</p> <p align="center">Alphapharm Pty Ltd</p>	<p align="center">Rheumatoid arthritis; Plaque psoriasis; Ankylosing spondylitis; Psoriatic arthritis; Juvenile idiopathic arthritis; Paediatric plaque psoriasis.</p>	<p align="center">To request listing of etanercept biosimilar under the same conditions as its reference biologic, with exclusion of children and adolescents who weigh less than 62.5 kg.</p>
New PBS listing	<p align="center">FLUTICASONE FUROATE WITH UMECLIDINIUM AND VILANTEROL</p> <p align="center">Powder for oral inhalation in breath actuated device containing fluticasone furoate 200 micrograms with umeclidinium 62.5 micrograms (as bromide) and vilanterol 25 micrograms (as trifenate) per dose, 30 doses</p> <p align="center">Trelegy® Ellipta® 200/62.5/25</p> <p align="center">GlaxoSmithKline Australia Pty Ltd</p>	<p align="center">Severe asthma</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of severe asthma.</p>

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Other business	<p align="center">FOLLITROPIN ALFA</p> <p align="center">Injection 300 I.U. in 0.5 mL multi-dose cartridge Injection 450 I.U. in 0.75 mL multi-dose cartridge Injection 900 I.U. in 1.5 mL multi-dose cartridge</p> <p align="center">Gonal-f® Pen</p> <p align="center">Merck Healthcare Pty Ltd</p>	Assisted reproductive technology	To request the PBAC consider the therapeutic relativities of Gonal-f® Pen and biosimilar therapies.
New PBS listing	<p align="center">GEMTUZUMAB OZOGAMICIN</p> <p align="center">Powder for Injection 5 mg</p> <p align="center">Mylotarg®</p> <p align="center">Pfizer Australia Pty Ltd</p>	Acute myeloid leukaemia (AML)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required listing for use in combination with standard intensive chemotherapy, for patients with previously untreated de novo CD33-positive AML, except acute promyelocytic leukaemia, who do not have a unfavourable cytogenetic profile.
New PBS listing	<p align="center">GILTERITINIB</p> <p align="center">Tablet 40 mg (as fumarate)</p> <p align="center">Xospata®</p> <p align="center">Astellas Pharma Australia Pty Ltd</p>	Acute myeloid leukaemia (AML)	To request a General Schedule Authority Required listing for the treatment of relapsed or refractory FLT3 mutation-positive AML.

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<p align="center">New PBS listing</p>	<p align="center"> IMATINIB Tablet 600 mg Imatab Juno Pharmaceuticals Pty Ltd </p>	<p> Chronic myeloid leukaemia (CML); Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL); Myelodysplastic or myeloproliferative disorder (MDS/MPD); Aggressive systemic mastocytosis (ASM) with eosinophilia; Chronic eosinophilic leukaemia (CEL) or Hypereosinophilic syndrome (HES); Dermatofibrosarcoma protuberans (DFSP); Gastrointestinal stromal tumour (GIST); Malignant GIST. </p>	<p align="center">To request listing of an additional strength under the same circumstances as the currently listed imatinib.</p>
<p align="center">New PBS listing</p>	<p align="center"> INSULIN ASPART Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5 Injections (human analogue), pre-filled pen, 100 units per mL, 3 mL, 5 Truvelog®; Truvelog® Solostar sanofi-aventis Australia Pty Ltd </p>	<p align="center">Diabetes mellitus</p>	<p align="center">To request listing of insulin aspart biosimilars under the same conditions as their reference brands.</p>

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Change to PBS listing	IXEKIZUMAB Injection 80 mg in 1 mL single dose pre-filled pen Taltz® Eli Lilly Australia Pty Ltd	Non radiographic axial spondyloarthritis (nr-axSpA)	To request a General Schedule Authority Required (Written) listing for the treatment of nr-axSpA, under the same circumstances as currently PBS listed biological disease-modifying antirheumatic agents for this indication.
New PBS listing	LAROTRECTINIB Capsule 25 mg Capsule 100 mg Oral solution 20 mg per mL, 100 mL Vitrakvi® Bayer Australia Ltd	Solid tumours harbouring neurotrophic receptor tyrosine kinase (NTRK) gene fusions	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of adult and paediatric patients with locally advanced or metastatic solid tumours harbouring NTRK gene fusions.
New PBS listing	MECASERMIN Solution for injection 40 mg in 4 mL vial Increlex® Ipsen Pty Ltd	Primary insulin-like growth factor 1 deficiency (Primary IGFD)	To request a Section 100 Authority Required (Written) listing for the treatment of children and adolescents with growth failure due to primary IGFD.
Change to PBS listing	MEPOLIZUMAB Injection 100 mg in 1 mL single dose pre-filled pen Nucala® GlaxoSmithKline Australia Pty Ltd	Chronic rhinosinusitis with nasal polyps	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of chronic rhinosinusitis with nasal polyps.

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Change to PBS listing	<p align="center">NIVOLUMAB</p> <p align="center">Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL</p> <p align="center">Opdivo®</p> <p align="center">Bristol-Myers Squibb Australia Pty Ltd</p>	<p align="center">Non-HER-2-positive gastric cancer, gastroesophageal junction cancer or oesophageal adenocarcinoma.</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first-line treatment of patients with advanced or metastatic non-HER-2-positive gastric cancer, gastroesophageal junction cancer or oesophageal adenocarcinoma.</p>
Change to PBS listing	<p align="center">OLAPARIB</p> <p align="center">Tablet 100 mg Tablet 150 mg</p> <p align="center">Lynparza®</p> <p align="center">AstraZeneca Pty Ltd</p>	<p align="center">Prostate cancer</p>	<p align="center">Resubmission to request a General Schedule Authority Required listing for the treatment of adult patients with metastatic castration-resistant prostate cancer and homologous recombination repair BRCA1/2 gene variants (somatic and/or germline) who have progressed following a prior novel hormonal agent.</p>
New PBS listing	<p align="center">OMALIZUMAB</p> <p align="center">Xolair®</p> <p align="center">Novartis Pharmaceuticals Australia Pty Limited</p>	<p align="center">Uncontrolled severe asthma; Severe chronic spontaneous urticaria; Uncontrolled severe allergic asthma.</p>	<p align="center">To combine the existing listings of 75 mg and 150 mg strengths to allow patients requiring 225mg and 375mg, respectively, to pay a single co-payment.</p>
Change to PBS listing	<p align="center">PEMBROLIZUMAB</p> <p align="center">Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p align="center">Keytruda®</p> <p align="center">Merck Sharp & Dohme (Australia) Pty Ltd</p>	<p align="center">Squamous cell carcinoma of the head and neck (SCCHN)</p>	<p align="center">Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first-line treatment of recurrent or metastatic SCCHN.</p>

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Change to PBS listing	<p align="center">PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p align="center">Keytruda®</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p>	<p align="center">Oesophageal carcinoma or HER-2-negative gastroesophageal adenocarcinoma</p>	<p>To request listing a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first-line treatment of locally advanced or metastatic oesophageal carcinoma or HER-2-negative gastroesophageal junction adenocarcinoma.</p>
New listing	<p align="center">PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE, 15 VALENT ADSORBED</p> <p align="center">0.5 mL in pre-filled syringe</p> <p align="center">Trade name to be confirmed</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p>	<p align="center">Prevention of pneumococcal disease</p>	<p>To request National Immunisation Program listing for the prevention of pneumococcal disease.</p>
Change to PBS listing	<p align="center">POLYETHYLENE GLYCOL 400 WITH PROPYLENE GLYCOL</p> <p align="center">Eye drops 4mg-3mg per mL, single dose units 0.8 mL, 30</p> <p align="center">Systane®</p> <p>Alcon Laboratories (Australia) Pty Ltd</p>	<p align="center">Severe dry eye syndrome</p>	<p>To request a change in pack size from a pack of 28 x 0.8 mL unit doses to 30 x 0.8 mL unit doses.</p>

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New PBS listing	PREGABALIN Tablet 82.5 mg Tablet 165 mg Tablet 330 mg Lyrica® CR Upjohn Australia Pty Ltd	Neuropathic pain	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of neuropathic pain in adults, where this condition is refractory to treatment with other drugs.
New PBS listing	PREGABALIN Oral solution 20 mg per mL, 473 mL Pregabalin-AFT AFT Pharmaceuticals (Au) Pty Ltd	Neuropathic pain	To request an Authority Required (STREAMLINED) listing of pregabalin solution under the same circumstances as the existing listings of pregabalin capsules.
Change to PBS listing	PROGESTERONE Pessary 200 mg Oripro® Orion Laboratories Pty Ltd	Prevention of preterm birth	To request an increase of maximum quantity from two packs (30 units) to three packs (45 units), and a decrease in number of repeats from five to three.
New PBS listing	REGORAFENIB Tablet 40 mg (as monohydrate) Stivarga® Bayer Australia Ltd	Colorectal cancer	Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for beyond second-line treatment of patients with metastatic colorectal cancer.

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New PBS listing	RISANKIZUMAB Injection 150mg in 1 mL pre-filled pen Injection 150mg in 1 mL pre-filled syringe Skyrizi® AbbVie Pty Ltd	Severe chronic plaque psoriasis	To request listing of new forms of risankizumab under the same circumstances as the currently listed risankizumab.
New PBS listing	RITUXIMAB Solution for I.V. infusion 100 mg in 10 mL Solution for I.V. infusion 500 mg in 50 mL Ruxience® Pfizer Australia Pty Ltd	Non-Hodgkin's lymphoma (NHL); Chronic lymphocytic leukaemia (CLL); Rheumatoid arthritis (RA); Granulomatosis with polyangiitis (Wegener's granulomatosis) (GPA); Microscopic polyangiitis (MPA).	To request listing of rituximab biosimilar under the same conditions as the currently listed rituximab.
New PBS listing	SACITUZUMAB GOVITECAN Powder for injection 180 mg Trodelvy® Gilead Sciences Pty Limited	Breast cancer	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 triple negative breast cancer, who have received two or more prior therapies, at least one of them in the locally advanced or metastatic setting.

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Submission type (new listing, change to listing)	Drug Name, form(s), strength(s) and Sponsor (Drug name, form, strength, Trade name®, Sponsor)	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.)
New PBS listing	<p align="center">SECUKINUMAB</p> 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 pen Injection 300 mg in 2 mL pre-filled syringe <p align="center">Cosentyx®</p> <p align="center">Novartis Pharmaceuticals Australia Pty Limited</p>	<p align="center">Paediatric psoriasis</p>	<p align="center">To request a General Schedule Authority Required (Written) listing for the treatment of paediatric patients with psoriasis, including the addition of a new 75 mg pre-filled syringe, 300 mg pre-filled pen and 300 mg pre-filled syringe.</p>
New PBS listing	<p align="center">TEPOTINIB</p> Tablet 225 mg (as hydrochloride monohydrate) <p align="center">Tepmetko®</p> <p align="center">Merck Healthcare Pty Ltd</p>	<p align="center">Non-small cell lung cancer (NSCLC)</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of patients with locally advanced or metastatic MET exon 14 skipping alterations-positive NSCLC.</p>
New PBS listing	<p align="center">TRASTUZUMAB</p> Powder for I.V. infusion 440 mg <p align="center">Herzuma®</p> <p align="center">Celltrion Healthcare Australia Pty Ltd</p>	Metastatic (Stage IV) HER2 positive breast cancer; Metastatic (Stage IV) HER2 positive adenocarcinoma of the stomach or gastroesophageal junction; Early HER2 positive breast cancer	<p align="center">To request listing of an additional strength under the same circumstances as the currently listed strengths of Herzuma.</p>

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New PBS listing	<p align="center">TRIENTINE</p> <p align="center">Tablet 150 mg (as tetrahydrochloride)</p> <p align="center">Cuprior®</p> <p align="center">Orphalan</p>	<p align="center">Wilson disease</p>	<p align="center">To seek a General Schedule Authority Required listing for the treatment of patients with Wilson disease who are intolerant to penicillamine.</p>
New PBS listing	<p align="center">TRIENTINE</p> <p align="center">Capsule 250 mg (as dihydrochloride)</p> <p align="center">Waymade®</p> <p align="center">Clinect Pty Ltd</p>	<p align="center">Wilson disease</p>	<p align="center">To seek a General Schedule Authority Required listing for the treatment of patients with Wilson disease who are intolerant to penicillamine.</p>
Sub-committee report (DUSC Analysis)	<p align="center">HIV antiretrovirals</p> <p align="center">All brands and strengths</p> <p align="center">Various sponsors</p>	<p align="center">Human immunodeficiency virus (HIV) infection</p>	<p align="center">To assess the utilisation of PBS listed HIV antiretrovirals.</p>
Sub-committee report (DUSC Analysis)	<p align="center">GOLIMUMAB</p> <p align="center">Simponi®</p> <p align="center">Janssen-Cilag Pty Ltd</p>	<p align="center">Non-radiographic axial spondyloarthritis</p>	<p align="center">To compare the predicted and actual utilisation of golimumab for the treatment of non-radiographic axial spondyloarthritis since PBS listing.</p>
Sub-committee report (DUSC Analysis)	<p align="center">NIVOLUMAB and IPILIMUMAB</p> <p align="center">Opdivo® and Yervoy®</p> <p align="center">Bristol-Myers Squibb Australia Pty Ltd</p>	<p align="center">Renal cell carcinoma</p>	<p align="center">To compare the predicted and actual utilisation of nivolumab and ipilimumab for the treatment of renal cell carcinoma since PBS listing.</p>

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Sub-committee report (DUSC Analysis)	PEMBROLIZUMAB Keytruda® Merck Sharp & Dohme (Australia) Pty Ltd	Urothelial cancer	To compare the predicted and actual utilisation of pembrolizumab for the treatment of urothelial cancer since PBS listing.
Sub-committee report (DUSC Analysis)	TOLVAPTAN Jinarc® Otsuka Australia Pharmaceutical Pty Ltd	Autosomal dominant polycystic kidney disease	To compare the predicted and actual utilisation of tolvaptan for the treatment of autosomal dominant polycystic kidney disease since PBS listing.
Review of positive PBAC recommendations not accepted by applicants	ADRENALINE I.M. injection 150 mcg in 0.3 mL single dose syringe auto-injector I.M. injection 300 mg in 0.3 mL single dose syringe auto-injector Adrenaline Auto Inject Sun-JV® AdrenaJect® Sun Pharma	Anaphylaxis	–
Review of positive PBAC recommendations not accepted by applicants	ALENDRONIC ACID Tablet, effervescent 70 mg Binosto® Pharmbio Pty Ltd	Osteoporosis	–

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Review of positive PBAC recommendations not accepted by applicants	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE Sachets containing oral powder 12.5 g, 30 MSUD Explore 5 Vitaflo Australia Pty Limited	Maple syrup urine disease (MSUD)	–
Review of positive PBAC recommendations not accepted by applicants	ARIPIPRAZOLE Powder for injection 400 mg (as monohydrate) with diluent pre-filled dual chamber syringe Abilify Maintena® Lundbeck Australia Pty Ltd	Schizophrenia	–
Review of positive PBAC recommendations not accepted by applicants	BUDESONIDE Capsule (modified release) 3 mg Budenofalk® Dr Falk Pharma Australia Pty Ltd	Mild to moderate Crohn disease	–
Review of positive PBAC recommendations not accepted by applicants	CANAKINUMAB Solution for injection 150 mg in 1 mL Ilaris® Novartis Pharmaceuticals Australia	Cryopyrin associated periodic syndromes (CAPS)	–

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Review of positive PBAC recommendations not accepted by applicants	CERTOLIZUMAB PEGOL Injection 200mg in 1 mL pre-syringe pen Solution for injection 200 mg in 1 mL pre-filled pen Cimzia® UCB Australia Pty Ltd	Severe chronic plaque psoriasis	–
Review of positive PBAC recommendations not accepted by applicants	CETUXIMAB Solution for IV infusion 100 mg in 20 mL, 500 mg in 100 mL Erbitux® Merck Australia Pty Ltd	Recurrent or metastatic squamous cell carcinoma of the head and neck	–
Review of positive PBAC recommendations not accepted by applicants	DENOSUMAB Injection 120 mg in 1.7 mL Xgeva® Amgen Australia Pty Ltd	Bisphosphonate-refractory hypercalcaemia of malignancy (HCM)	–
Review of positive PBAC recommendations not accepted by applicants	HIGH DOSE INACTIVATED TRIVALENT INFLUENZA VACCINE (SPLIT VIRION) Injection 0.5 mL Fluzone® High-Dose sanofi-aventis Australia Pty Ltd	National Immunisation Program (NIP) listing for the prevention of seasonal influenza in patients aged 65 years and over	–

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Review of positive PBAC recommendations not accepted by applicants	IBRUTINIB Capsule 140 mg Imbruvica® Janssen-Cilag Pty Ltd	Chronic lymphocytic leukaemia (CLL) and small lymphocytic lymphoma (SLL)	–
Review of positive PBAC recommendations not accepted by applicants	PACLITAXEL, NANOPARTICLE ALBUMIN-BOUND Powder for I.V. injection containing 250 mg paclitaxel Abraxane® Specialised Therapeutics Australia Pty Ltd	Adenocarcinoma of the pancreas and breast cancer	–
Review of positive PBAC recommendations not accepted by applicants	PARITAPREVIR with RITONAVIR with OMBITASVIR Tablet 75 mg-50 mg-12.5 mg Technivie® AbbVie Pty Ltd	Hepatitis C	–
Review of positive PBAC recommendations not accepted by applicants	RADIUM (223Ra) Injection containing radium (233Ra) dichloride 6.6 MBq/6 mL Xofigo® Bayer Australia Ltd	Metastatic castrate resistant prostate cancer	–

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Review of positive PBAC recommendations not accepted by applicants	<p align="center">SARILUMAB</p> <p align="center">Injection 150 mg in 1.14 mL pre-filled syringe Injection 200 mg in 1.14 mL pre-filled syringe</p> <p align="center">Kevzara®</p> <p align="center">sanofi-aventis Australia Pty Ltd</p>	<p align="center">Rheumatoid arthritis</p>	<p align="center">–</p>
New PBS listing	<p align="center">BUDESONIDE</p> <p align="center">Tablet (orally disintegrating) 0.5 mg Tablet (orally disintegrating) 1 mg</p> <p align="center">Jorveza®</p> <p align="center">Dr Falk Pharma Australia Pty Ltd</p>	<p align="center">Eosinophilic oesophagitis (EoE)</p>	<p align="center">Resubmission to request an Authority Required listing for the treatment of EoE.</p>
New PBS listing	<p align="center">SILTUXIMAB</p> <p align="center">Powder for injection 100 mg Powder for injection 400 mg</p> <p align="center">Sylvant®</p> <p align="center">Eusa Pharma (UK) Ltd</p>	<p align="center">Idiopathic multicentric Castleman's disease (iMCD)</p>	<p align="center">Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of iMCD.</p>

Version 6

Amendment

1. CEMIPILIMAB (Squamous cell carcinoma) agenda item has been withdrawn.
2. CEMIPILIMAB (Squamous cell carcinoma) agenda item changed from withdrawn to *To be considered at a future PBAC meeting.*

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3. ABROCITINIB (Atopic dermatitis) agenda item changed to To be considered at a future PBAC meeting.

Items added or amended previously (Version 2, 3, 4, 5)

- Added – Two (2) Early Re-entry resubmissions received (page 23).
- Added – Fifteen (15) items scheduled for review under the process for reviewing positive PBS-listing recommendations not accepted by applicants (pages 19–23).
- Added – OMALIZUMAB.
- Added – NIVOLUMAB (Non-HER-2-positive gastric cancer, gastroesophageal junction cancer or oesophageal adenocarcinoma).
- Amended - FLUTICASON E FUROATE WITH UMECLIDINIUM AND VILANTEROL: strength amended to *200/62.5/25* from *100/62.5/25*, and 'submission type' replaced with *New PBS listing*.
- Amended – ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS: Drug form changed from Sachets containing oral powder 12.5 g, 50 to Sachets containing oral powder 12.5 g, 30. Wording regarding maximum quantity amended under 'purpose of submission'.
- Amended – ACALABRUTINIB: deleted *in combination*, replaced with *and unsuitable for venetoclax in combination with obinutuzumab* under 'purpose of submission'.