PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
July 2022 PBAC MEETING

Closing date for consumer comments 25th May 2022

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.
- *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.

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 All PBS-listed forms Yuflyma® Celltrion Healthcare Australia Pty Ltd (New PBS 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 listing of adalimumab biosimilar under the same conditions as its reference biologic.
ANIFROLUMAB Solution concentrate for I.V. infusion 300 mg in 2 mL Saphnelo® AstraZeneca Pty Ltd (New PBS listing)	Systemic lupus erythematosus	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of patients with systemic lupus erythematosus with a high degree of disease activity despite standard therapy.

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APALUTAMIDE Tablet 60 mg Erlyand® Janssen-Cilag Pty Ltd (Change to recommended PBS listing)	Prostate cancer	Resubmission 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.
ASCIMINIB Tablet 20 mg Tablet 40 mg Scemblix® Novartis Pharmaceuticals Australia Pty Limited (New PBS listing)	Chronic myeloid leukaemia	To request a General Schedule Authority Required listing for the treatment of patients with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase previously treated with two or more tyrosine kinase inhibitors.
ATEZOLIZUMAB Solution concentrate for I.V. infusion 840 mg in 14 mL Solution concentrate for I.V. infusion 1200 mg in 20 mL Tecentriq® Roche Products Pty Ltd (Change to PBS listing)	Non-small cell lung cancer	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing as adjuvant treatment in patients with programmed cell death ligand-1 (PD-L1) positive Stage II-IIIA non-small cell lung cancer following complete resection and platinum-based chemotherapy.

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AZACITIDINE Tablet 200 mg Tablet 300 mg Onureg® Celgene Pty Limited (New PBS listing)	Acute myeloid leukaemia	To request a General Schedule Authority Required (STREAMLINED) listing for maintenance therapy in certain patients with acute myeloid leukaemia who are not candidates for, including those who choose not to proceed to, haematopoietic stem cell transplantation.
BECLOMETASONE WITH FORMOTEROL Pressurised inhalation containing beclometasone dipropionate 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses Fostair® 200/6 Chiesi Australia Pty Ltd (New PBS listing)	Asthma	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of asthma in certain patients previously treated with oral corticosteroids or optimal doses of inhaled corticosteroids.
CANNABIDIOL Oral liquid 100 mg per mL, 100 mL Epidyolex® Chiesi Australia Pty Ltd (Change to PBS listing)	Lennox-Gastaut syndrome	Resubmission to request a General Schedule Authority Required listing for the adjunctive treatment of seizures in patients with Lennox-Gastaut syndrome (LGS) aged 2 years and older.

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CEMIPLIMAB Solution for I.V. infusion 350 mg in 7 mL Libtayo® Sanofi-Aventis Australia Pty Ltd (Change to recommended PBS listing)	Cervical cancer	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.
DAUNORUBICIN WITH CYTARABINE Powder for I.V. infusion containing daunorubicin 44 mg and cytarabine 100 mg Vyxeos® Jazz Pharmaceuticals ANZ Pty Ltd (New PBS listing)	Acute myeloid leukemia	To request a Section 100 (Efficient Funding of Chemotherapy Program) Restricted Benefit listing for the treatment of therapy-related acute myeloid leukaemia and acute myeloid leukaemia with myelodysplasia-related changes.
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 (Other matters)	Chronic severe atopic dermatitis	To request the PBAC consider the previously estimated utilisation for chronic severe atopic dermatitis.

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EPTINEZUMAB Solution concentrate for I.V. infusion 100 mg in 1 mL Vyepti® Lundbeck Australia Pty Ltd (New PBS listing)	Chronic migraine	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of chronic migraine.
ESKETAMINE Nasal spray solution 28 mg in 0.2 mL Spravato® Janssen-Cilag Pty Ltd (New PBS listing)	Depression	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of treatment-resistant depression.
EVOLOCUMAB Injection 140 mg in 1 mL single use pre-filled pen Injection 420 mg in 3.5 mL single use pre-filled cartridge Repatha® Amgen Australia Pty Limited (Change to PBS listing)	Hypercholesterolaemia	To request a change to the low-density lipoprotein cholesterol criterion on the existing PBS evolocumab listings for hypercholesterolaemia from 2.6 mmol/L to 1.8 mmol/L, and also to extend the existing listings to allow general practitioners to initiate treatment in consultation with a specialist physician.

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FINERENONE Tablet 10 mg Tablet 20 mg Kerendia® Bayer Australia Ltd (New PBS listing)	Diabetic kidney disease	To request a General Schedule Authority Required (STREAMLINED) listing for patients with diabetic kidney disease.
HUMAN MENOPAUSAL GONADOTROPHIN Injection 600 I.U. in 0.96 mL pre-filled multi-dose pen Injection 1200 I.U. in 1.92 mL pre-filled multi-dose pen Menopur® 600 Menopur® 1200 Ferring Pharmaceuticals Pty Limited (New PBS listing)	Assisted Reproductive Technology	To request Section 100 (IVF Program) listing of a new form under the same conditions as the currently listed form of human menopausal gonadotrophin.

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LEUPRORELIN ACETATE Suspension for subcutaneous injection (modified release) containing 45 mg of leuprorelin acetate Eligard® 6 month Mundipharma Pty Limited (Change to PBS listing)	Central precocious puberty	To request a General Schedule Restricted Benefit listing for the treatment of central precocious puberty.
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 (New PBS listing)	Epilepsy	To request a General Schedule Authority Required listing for the treatment of generalised convulsive status epilepticus.

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NATALIZUMAB Solution concentrate for I.V. infusion 300 mg in 15 mL Tysabri® Biogen Australia Pty Ltd (Change to PBS listing)	Multiple sclerosis	To request removal of the clinical criterion which requires neurologists prescribing natalizumab under the PBS to be registered with the Tysabri Australian Prescribing Program.
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 PBS listing)	Urothelial carcinoma	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required listing for adjuvant treatment of patients who have undergone radical resection of muscle invasive urothelial carcinoma originating in the bladder or upper urinary tract (renal pelvis or ureter) and are at high risk of recurrence.

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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® Bristol-Myers Squibb Australia Pty Ltd (Change to PBS listing)	Oesophageal carcinoma or gastroesophageal junction carcinoma	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required listing for the adjuvant treatment of patients with oesophageal carcinoma or gastroesophageal junction carcinoma who have previously received platinum-based chemoradiotherapy and surgery.
OLAPARIB Tablet 100 mg Tablet 150 mg Lynparza® AstraZeneca Pty Ltd (Change to PBS listing)	Ovarian cancer	To request a General Schedule Authority Required listing for use in combination with bevacizumab for maintenance therapy in patients with newly diagnosed homologous recombination deficiency (HRD) positive BRCA wild type advanced epithelial ovarian, fallopian tube or primary peritoneal cancer.

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PEGCETACOPLAN Solution for subcutaneous infusion 1,080 mg in 20 mL Empaveli™ Swedish Orphan Biovitrum Pty Ltd (New PBS listing)	Paroxysmal nocturnal haemoglobinuria	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of adults with paroxysmal nocturnal haemoglobinuria who have an inadequate clinical response to complement component 5 (C5) inhibitor treatment.
PEGVALIASE Solution for injection 2.5 mg in 0.5 mL Solution for injection 10 mg in 0.5 mL Solution for injection 20 mg in 1 mL Palynziq® BioMarin Pharmaceutical Australia Pty Ltd (New PBS listing)	Phenylketonuria	To request a General Schedule Authority Required listing for the treatment of hyperphenylalaninemia due to phenylketonuria in patients aged 16 years and over who are not responsive to sapropterin.
PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® Merck Sharp & Dohme (Australia) Pty Ltd (Change to PBS listing)	Urothelial cancer Colorectal cancer Primary Mediastinal B-cell Lymphoma Classical Hodgkin Lymphoma	To request addition of a new dosing regimen of 400 mg every 6 weeks (Q6W) for pembrolizumab for urothelial cancer, colorectal cancer, primary mediastinal B-cell lymphoma and classical hodgkin lymphoma indications. The submission also requested that Q6W dosing be extended to potential future pembrolizumab listings for squamous cell carcinoma of the head and neck (SCCHN) and oesophageal carcinoma which were considered by PBAC at its March 2022 meeting.

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POLYETHYLENE GLYCOL 400 WITH PROPYLENE GLYCOL Eye drops 4 mg-3 mg per mL, 15 mL Optix® Petrus Pharmaceuticals Pty Ltd (New PBS listing)	Severe dry eye syndrome, including Sjogren's syndrome	To request a General Schedule Restricted Benefit listing of a new brand under the same conditions as the currently listed brand of polyethylene glycol 400 with propylene glycol.
PROGESTERONE Pessary 400 mg Cyclogest® Gedeon Richter Australia Pty Ltd (New PBS listing)	Infertility	To request a Section 100 (IVF Program) Authority Required (STREAMLINED) listing for luteal phase support as part of an assisted reproductive technology treatment cycle for infertile women.
RELATLIMAB WITH NIVOLUMAB Injection concentrate for I.V. infusion containing 80 mg relatlimab and 240 mg nivolumab in 20 mL Opdualag® Bristol-Myers Squibb Australia Pty Ltd (New PBS listing)	Melanoma	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of Stage III or IV metastatic melanoma.

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RISANKIZUMAB Solution concentrate for I.V. infusion 600 mg in 10 mL Injection 360 mg in 2.4 mL in pre-filled cartridge Skyrizi® AbbVie Pty Ltd (New PBS listing)	Crohn disease	To request General Schedule Authority Required (Written) listings for the treatment of severe Crohn disease and for complex refractory fistulising Crohn disease.
ROMOSOZUMAB Injection 105 mg in 1.17 mL single use pre-filled syringe Evenity® Amgen Australia Pty Limited (Change to PBS listing)	Osteoporosis	Resubmission to request a General Schedule Authority Required listing for the first-line treatment of patients with severe osteoporosis at very high risk of fracture. The submission also requests an expansion to the current second-line PBS listing by removing the requirement for patients to have had two or more fractures and by reducing the Bone Mineral Density T-score threshold from ≤ -3 to ≤ -2.5.

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RUXOLITINIB Tablet 5 mg Tablet 10 mg Jakavi® Novartis Pharmaceuticals Australia Pty Limited (Change to PBS listing)	Graft versus host disease	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of patients aged 12 years and older with Grade II to Grade IV acute graft versus host disease (GVHD) or moderate to severe chronic GVHD who are refractory to, dependent on or intolerant of corticosteroids.
SAPROPTERIN Tablet (soluble) containing sapropterin dihydrochloride 100 mg Powder for oral solution 500 mg (as dihydrochloride) Kuvan® BioMarin Pharmaceutical Australia Pty Ltd (Change to PBS listing)	Phenylketonuria	To request an extension to the current PBS listing for sapropterin for the treatment of hyperphenylalaninemia due to phenylketonuria to allow adults to be eligible for sapropterin responsiveness testing and continuing treatment for those who are sapropterin responsive.

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TEZEPELUMAB Injection 210 mg in 1.91 mL single use pre-filled pen Tezspire® AstraZeneca Pty Ltd (New PBS listing)	Asthma	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for patients with severe uncontrolled allergic and/or eosinophilic asthma.
TRASTUZUMAB DERUXTECAN Powder for I.V. infusion 100 mg Enhertu® AstraZeneca Pty Ltd (New PBS listing)	Breast cancer	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Written) listing for the treatment of human epidermal growth factor receptor 2 positive (HER2) metastatic breast cancer in patients whose disease has progressed following treatment with at least one prior HER2-directed regimen in the metastatic setting or whose disease has progressed during or within 6 months following HER2-directed adjuvant treatment.
UPADACITINIB Tablet 15 mg Tablet 30 mg Tablet 45 mg Rinvoq® AbbVie Pty Ltd (Change to PBS listing)	Ulcerative colitis	To request a General Schedule Authority Required (Written) listing for the treatment of moderate to severe ulcerative colitis, in patients who are contraindicated to, or whose disease has not adequately responded to conventional therapies.

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USTEKINUMAB Injection 90 mg in 1 mL pre-filled syringe Stelara® Janssen-Cilag Pty Ltd (New PBS listing)	Severe Crohn disease Severe chronic plaque psoriasis	To request a General Schedule Authority Required (Written) listing of a new form for the treatment of patients with Crohn disease and chronic plaque psoriasis.
USTEKINUMAB Injection 90 mg in 1 mL pre-filled syringe Solution concentrate for I.V. infusion 130 mg in 26 mL Stelara® Janssen-Cilag Pty Ltd (New PBS listing)	Ulcerative colitis	To request General Schedule and Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listings for the treatment of moderate to severe ulcerative colitis, in patients who are contraindicated to, or whose disease has not adequately responded to conventional therapies.
VERICIGUAT Tablet 2.5 mg Tablet 5 mg Tablet 10 mg Verquvo® Bayer Australia Ltd (New PBS listing)	Chronic heart failure	Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of symptomatic (NYHA class II, III or IV) chronic heart failure in patients with a reduced ejection fraction (left ventricular ejection fraction less than 45%) and who are stabilised after a recent decompensation heart failure event requiring hospitalisation and/or intravenous diuretic therapy.

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VOSORITIDE Powder for injection 0.4 mg with diluent Powder for injection 0.56 mg with diluent Powder for injection 1.2 mg with diluent Voxzogo® BioMarin Pharmaceutical Australia Pty Ltd (New PBS listing)	Achondroplasia	To request a General Schedule Authority Required listing for the treatment of patients with achondroplasia whose epiphyses are not closed.
Proton Pump Inhibitors medicines All brands and strengths Various sponsors (Sub-committee report DUSC Analysis)	Gastrointestinal acid related disorders	To review recent utilisation of PBS-listed proton pump inhibitor (PPI) medicines used in the management of gastrointestinal acid related disorders.
Teduglutide 5 mg injection [28 vials] (&) inert substance diluent [28 x 0.5 mL syringes] Revestive® Takeda Pharmaceuticals Australia Pty. Ltd (Sub-committee report DUSC Analysis)	Type III Short Bowel Syndrome with intestinal failure	To compare the predicted and actual utilisation of teduglutide for Type III Short Bowel Syndrome with intestinal failure in the first 24 months of PBS listing.

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EXANATIDE DULAGLUTIDE SEMAGLUTIDE All brands and strengths AstraZeneca Pty Ltd Eli Lilly Australia Pty Ltd Novo Nordisk Pharmaceuticals Pty Ltd (Clinical and cost utility review)	Type 2 diabetes mellitus	To assess the clinical and cost utility of glucagon-like peptide-1 (GLP-1) receptor agonists for the treatment of type 2 diabetes mellitus in the Australian setting.
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 cell lung cancer, relapsed or recurrent glioblastoma, epithelial ovarian, fallopian tube or primary peritoneal cancer, cervical cancer	-
BIMATOPROST 300 micrograms per mL, 3 mL Vizo-PF Bimatoprost® AFT Pharmaceuticals Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Elevated intraocular pressure or open angle glaucoma	-

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ENOXAPARIN 120 mg/mL injection, 10 x 0.8 mL syringes 150 mg/mL injection, 10 x 1 mL syringes Clexane Forte® Enoxaparin Winthrop® Clexane Forte Safety-Lock® Sanofi-Aventis Australia Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Thromboembolic disorders in patients undergoing surgery, prophylaxis of venous thromboembolism, prevention of thrombosis during haemodialysis, deep vein thrombosis, unstable angina, non-Q-wave myocardial infarction, acute ST-segment elevation myocardial infarction as an adjunctive to thrombolytic treatment	-
GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID WITH LOW PHENYLALANINE Sachets containing oral powder 33.3 g PKU GMPro® Nutricia Australia Pty Limited (Review of positive PBAC recommendations not accepted by applicants)	Phenylketonuria	-

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INSULIN ASPART Injection (human analogue) cartridges, 100 units per mL, 3 mL Fiasp® Novo Nordisk Pharmaceuticals Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Diabetes mellitus	-
RAMUCIRUMAB Injection concentrate for I.V. infusion 100 mg in 10 mL Injection concentrate for I.V. infusion 500 mg in 50 mL Cyramza® Eli Lily Australia Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Gastric or gastro-oesophageal junction adenocarcinoma	-

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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.)
SECUKINUMAB Powder for injection, 150 mg Pre-filled syringe, 150 mg per mL Cosentyx® Novartis Pharmaceuticals (Review of positive PBAC recommendations not accepted by applicants)	Plaque psoriasis	-
SEVELAMER Sachet 2.4 g Renvela® Sanofi-Aventis Australia Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Hyperphosphataemia in patients undergoing dialysis for chronic kidney disease	-

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
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TENOFOVIR ALAFENAMIDE Tablet 25 mg Vemlidy® Gilead Sciences Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Hepatitis B	-

Version 2

Items added

1. Three (3) Early Re-entry resubmissions received (pages 4, 11 and 16)
2. Nine (9) items scheduled for review under the process for reviewing positive PBS-listing recommendations not accepted by applicants (pages 18–22).
3. DUPILUMAB (Dupixent®) for chronic severe atopic dermatitis – Submission type has been amended to 'Other matters' from 'Change to PBS listing'.
4. TEZEPELUMAB (Tezspire®) for asthma – form amended to 'pre-filled pen' from 'pre-filled syringe'.