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

Closing date for consumer comments 25 January 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.

- *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 PBS listing)	Breast cancer	Resubmission to request a General Schedule Authority Required (telephone/online) listing for use in combination with standard adjuvant endocrine therapy for the treatment of hormone receptor positive (HR+), human epidermal growth factor receptor 2 negative (HER2-), lymph node-positive, invasive, resected early breast cancer at high risk of disease recurrence.

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ACALABRUTINIB Capsule 100 mg Calquence® AstraZeneca Pty Ltd (Other matters)	Relapsed or refractory chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL).	To request the PBAC consider the previously estimated utilisation for relapsed or refractory CLL or SLL.
ALIROCUMAB Injection 300 mg in 2 mL single dose autoinjector Praluent® Sanofi-Aventis Australia Pty Ltd (New PBS listing)	Familial heterozygous hypercholesterolaemia and non-familial hypercholesterolaemia.	To request listing of a new form and strength under the same conditions as the currently listed form and strengths of alirocumab for the treatment of familial heterozygous hypercholesterolaemia and non-familial hypercholesterolaemia.

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AMINO ACID FORMULA WITH VITAMINS AND MINERALS, WITHOUT METHIONINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID Sachets containing oral powder 12.5 g, 30 (HCU Explore5) HCU Explore5 Vitaflo Australia Pty Limited (New PBS listing)	Pyridoxine non-responsive homocystinuria (HCU)	To request a General Schedule Restricted Benefit listing for the dietary management of HCU.
AMINO ACID FORMULA WITH VITAMINS AND MINERALS, WITHOUT PHENYLALANINE AND TYROSINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID Sachets containing oral powder 12.5 g, 30 (TYR Explore5) TYR Explore5 Vitaflo Australia Pty Limited (New PBS listing)	Tyrosinaemia	To request a General Schedule Restricted Benefit listing for the dietary management of tyrosinaemia.

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AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID Sachets containing oral powder 12.5 g, 30 (MSUD Explore5) MSUD Explore5 Vitaflo Australia Pty Limited (New PBS listing)	Maple syrup urine disease (MSUD)	To request a General Schedule Restricted Benefit listing for the dietary management of patients with MSUD.
AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS Oral powder 400 g (EleCare LCP) EleCare® LCP Abbott Australasia Pty Ltd (Change to PBS listing)	Cows' milk protein enteropathy Severe cows' milk protein enteropathy with failure to thrive Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae Cows' milk anaphylaxis Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein Severe intestinal malabsorption including short bowel syndrome	To request that EleCare LCP with new source of docosahexaenoic acid (DHA) continue to be listed on the PBS under the current conditions.

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ANIFROLUMAB Solution concentrate for I.V. infusion 300 mg in 2 mL vial Saphnelo® AstraZeneca Pty Ltd (New PBS listing)	Systemic lupus erythematosus (SLE)	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (written) listing for the treatment of severe SLE with a high degree of disease activity despite standard therapy.
APREMILAST Tablet 30 mg Pack containing 4 tablets of 10 mg, 4 tablets of 20 mg and 19 tablets of 30 mg Otezla® Amgen Australia Pty Limited (Change to PBS listing)	Psoriatic arthritis (PsA)	To request a General schedule Authority Required (STREAMLINED) listing for the treatment of severe active PsA.

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BIMEKIZUMAB Injection 160 mg in 1 mL single use pre-filled syringe Injection 160 mg in 1 mL single use pre-filled pen Bimzelx® UCB Australia Proprietary Limited (New PBS listing)	Chronic plaque psoriasis	To request a General Schedule Authority Required (written) listing for the treatment of chronic plaque psoriasis.
BUDESONIDE Tablet 500 micrograms (orally disintegrating) Tablet 1 mg (orally disintegrating) Jorveza® Dr Falk Pharma Australia Pty Ltd (Change to PBS listing)	Eosinophilic oesophagitis (EoE)	To request PBAC advice regarding the number of biopsies to confirm eligibility for initial treatment; removal of the histological assessment to determine eligibility for continuing treatment; and an expansion to the treatment criteria to include physicians or surgeons experienced in the diagnosis and management of EoE.

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CARMELLOSE WITH GLYCERIN AND WITH HYALURONIC ACID Eye drops containing carmellose sodium 5 mg with glycerin 9 mg and with hyaluronic acid 1 mg per mL, 10 mL Optive Fusion® Allergan Australia Pty Limited (New PBS listing)	Severe dry eye syndrome	To request a General Schedule Restricted Benefit listing for the treatment of severe dry eye syndrome.
CHLORMETHINE HYDROCHLORIDE 0.016% (160 microgram/g) gel Ledaga® Juniper Biologics Pty Ltd (New PBS listing)	Mycosis fungoides-type cutanous T-cell lymphoma (MF-type CTCL)	To request a General Schedule Authority Required (telephone/electronic) listing for the treatment of adults with MF-type CTCL.

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DARATUMUMAB Solution for I.V. infusion 100 mg in 5 mL vial Solution for I.V. infusion 400 mg in 20 mL vial Solution for S.C. injection 1,800 mg in 15 mL vial Darzalex® Janssen-Cilag Pty Ltd (Change to PBS listing)	Multiple myeloma	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (telephone/online) listing for the I.V. and S.C. formulations and a General Schedule Authority Required (telephone/online) listing for the S.C. formulation for use in combination with lenalidomide and dexamethasone for the treatment of transplant ineligible, newly diagnosed multiple myeloma.
DIFELIKEFALIN Solution for I.V. injection 50 mcg in 1 mL vial Korsuva® Vifor Pharma Pty Limited (New PBS 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 in adult patients on haemodialysis.

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DURVALUMAB Solution concentrate for I.V. infusion 120 mg in 2.4 mL vial Solution concentrate for I.V. infusion 500 mg in 10 mL vial Imfinzi® AstraZeneca Pty Ltd (Change to PBS listing)	Biliary tract cancer	To request a Section 100 (Efficient Funding of Chemotherapy program) Authority Required (STREAMLINED) listing for the treatment of advanced biliary tract cancer.
ENZALUTAMIDE Capsule 40 mg Xtandi® Astellas Pharma Australia Pty Ltd (Change to PBS listing)	Prostate cancer	To request a General Schedule Authority Required (telephone/online) listing for the treatment of metastatic hormone-sensitive prostate cancer in patients with low volume disease, and in high volume disease where the patient is unsuitable for docetaxel due to poor ECOG status, comorbidities, or contraindications.

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FINERENONE Tablet 10 mg Tablet 20 mg Kerendia® Bayer Australia Ltd (New PBS listing)	Chronic kidney disease in Type 2 diabetes	Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of chronic kidney disease in patients with type 2 diabetes mellitus.
FOSNETUPITANT (AS CHLORIDE HYDROCHLORIDE)/PALONOSETRON (AS HYDROCHLORIDE) Solution concentrate for I.V. infusion containing fosnetupitant 235 mg and palonosetron 0.25 mg in 20 mL vial Akynzeo®IV Juniper Biologics Pty Ltd (New PBS listing)	Nausea and vomiting	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) and a General Schedule Authority Required (STREAMLINED) listing for the treatment of nausea and vomiting in patients receiving highly, or moderately, emetogenic chemotherapy.

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GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS Oral liquid 250 mL, 30 (Tylactin RTD) Tylactin® RTD Cortex Health Pty Ltd (Other matters)	Tyrosinaemia	To request Tylactin RTD with new formulation continue to be listed on the PBS under the existing conditions.
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS Sachets containing oral powder 40 g, 30 (Camino Pro Bettermilk) Oral liquid 250 mL, 30 (PKU Glytactin RTD 15) Camino Pro® Bettermilk PKU Glytactin RTD 15 Cortex Health Pty Ltd (New PBS listing)	Phenylketonuria	To request Camino Pro Bettermilk and PKU Glytactin RTD 15 with new formulation continue to be listed on the PBS under the existing conditions. The submission also requested a new pack size for Camino Pro Bettermilk of 30 x 40 g sachets.

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HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE Oral liquid 250 mL, 30 (KetoVie 3:1) Oral liquid 250 mL, 30 (KetoVie 4:1) Oral liquid 250 mL, 30 (KetoVie Peptide 4:1) KetoVie® 3:1 KetoVie® 4:1 KetoVie® Peptide 4:1 Cortex Health Pty Ltd (Other matters)	Ketogenic diet	To request KetoVie 3:1, KetoVie 4:1, and KetoVie Peptide 4:1 with new formulation continue to be listed on the PBS under the existing conditions.
HYALURONIC ACID WITH POLYETHYLENE GLYCOL 400 WITH PROPYLENE GLYCOL WITH HYDROXYPROPYL GUAR Eye drops containing sodium hyaluronate 1.5 mg per mL with polyethylene glycol 400, propylene glycol and hydroxypropyl guar, 10 mL Systane® Hydration Alcon Laboratories (Australia) Pty Ltd (New PBS listing)	Severe dry eye syndrome	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.

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INCLISIRAN Injection 284 mg in 1.5 mg single use pre-filled syringe Leqvio® Novartis Pharmaceuticals Australia Pty Limited (New PBS listing)	Hypercholesterolaemia	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of hypercholesterolaemia and atherosclerotic cardiovascular disease.
LAROTRECTINIB Oral solution 20 mg per mL, 50 mL, 2 Vitrakvi® Bayer Australia Ltd (New PBS listing) WITHDRAWN	Solid tumours harbouring neurotrophic receptor tyrosine kinase (NTRK) gene fusions	To request listing a new form and formulation of oral solution under the existing conditions to replace the currently listed oral solution of larotrectinib.

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MIFEPRISTONE AND MISOPROSTOL Pack containing 1 tablet mifepristone 200 mg and 4 tablets misoprostol 200 micrograms MS-2 Step® MS Health Pty Ltd (Change to PBS listing)	Termination of an intrauterine pregnancy	To request a change to the restriction level of the existing listing from Authority Required to Authority Required (STREAMLINED) for termination of an intrauterine pregnancy.
NATALIZUMAB Injection 150 mg in 1 mL single dose pre-filled syringe Tysabri® Biogen Australia Pty Ltd (New PBS listing)	Relapsing-remitting multiple sclerosis (RRMS)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing of a new form of natalizumab for the treatment of RRMS.

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NETUPITANT WITH PALONOSETRON Capsule containing netupitant 300 mg with palonosetron 500 microgram (as hydrochloride) Akynzeo® Juniper Biologics Pty Ltd (Change to PBS listing)	Nausea and vomiting	To request a change to the clinical criteria to align restrictions with the National Comprehensive Cancer Network Guidelines for the treatment of nausea and vomiting.
NIRAPARIB Capsule 100 mg Zejula® GlaxoSmithKline Australia Pty Ltd (Change to PBS listing)	Epithelial ovarian, fallopian tube, or primary peritoneal cancer	To request an expanded General Schedule Authority Required (telephone/online) listing for the treatment of newly diagnosed, homologous recombination deficiency (HRD) positive, BRCA wild type advanced (FIGO Stage III-IV) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer.

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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 (Other matters)	Gastro-oesophageal cancers	To request that first-line oesophageal squamous cell carcinoma (OSCC) patients are included in the financial estimates for the treatment of advanced or metastatic gastro-oesophageal cancers.
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)	Non-small cell lung cancer (NSCLC)	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the neoadjuvant treatment of resectable NSCLC.

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OLAPARIB Tablet 100 mg Tablet 150 mg Lynparza® AstraZeneca Pty Ltd (New PBS listing)	Breast cancer	To request a General Schedule Authority Required (telephone/online) listing for the treatment of human epidermal growth factor 2 (HER2)-negative high risk early breast cancer with a confirmed germline BRCA1 or BRCA2 mutation who have previously been treated with neoadjuvant or adjuvant chemotherapy.
OSILODROSTAT Tablet 1 mg Tablet 5 mg Tablet 10 mg Isturisa® Recordati Rare Diseases Australia Pty. Ltd. (New PBS listing)	Cushing syndrome	To request a General Schedule Authority Required (telephone/online) listing for the treatment of adult patients with endogenous Cushing syndrome who are not candidates for surgery or for whom surgery was not curative.

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PATIROMER Sachet, 8.4 g powder for oral liquid Sachet, 16.8 g powder for oral liquid Veltassa® Vifor Pharma Pty Limited (New PBS listing)	Hyperkalaemia	Resubmission to request a General Schedule Authority Required listing for the treatment of chronic hyperkalaemia in patients with stage 3 or stage 4 chronic kidney disease.
PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL vial Keytruda® Merck Sharp & Dohme (Australia) Pty Ltd (Change to PBS listing)	Breast cancer	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of locally recurrent unresectable or metastatic triple negative breast cancer.
PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL vial Keytruda® Merck Sharp & Dohme (Australia) Pty Ltd (Change to PBS listing)	Breast cancer	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of early stage triple negative breast cancer in patients who have not received prior systemic therapy.

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PEMETREXED Solution concentrate for I.V. infusion 100 mg in 4 mL vial Solution concentrate for I.V. infusion 500 mg in 20 mL vial Solution concentrate for I.V. infusion 1000 mg in 40 mL vial Pemetrexed EVER Pharma Interpharma Pty Ltd (New PBS listing)	Mesothelioma Locally advanced or metastatic non-small cell lung cancer	To request listing a new form of pemetrexed under the existing conditions as the currently listed pemetrexed powder for I.V. infusion.
PNEUMOCOCCAL CONJUGATE VACCINE, 15 VALENT ADSORBED 0.5 mL pre-filled syringe Vaxneuvance® Merck Sharp & Dohme (Australia) Pty Ltd (New PBS listing)	Prevention of pneumococcal disease	To request a National Immunisation Program listing for the prevention of pneumococcal disease in paediatrics.

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RAVULIZUMAB Solution concentrate for I.V. infusion 300 mg in 3 mL vial Solution concentrate for I.V. infusion 1.1 g in 11 mL vial Ultomiris® Alexion Pharmaceuticals Australasia Pty Ltd (Change to PBS listing)	Atypical haemolytic uraemic syndrome (aHUS)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (written) listing for the treatment of aHUS.
RELATLIMAB AND NIVOLUMAB Solution concentrate for I.V. infusion containing 80 mg relatlimab and 240 mg nivolumab in 20 mL vial Opdualag® Bristol-Myers Squibb Australia Pty Ltd (New PBS listing)	Melanoma	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of unresectable Stage III or Stage IV malignant melanoma.

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RIOCIGUAT 500 microgram tablet, 84 1 mg tablet, 84 1.5 mg tablet, 84 2 mg tablet, 84 2.5 mg tablet, 84 Adempas® Bayer Australia Ltd (Change to PBS listing) WITHDRAWN	Pulmonary arterial hypertension Chronic thromboembolic pulmonary hypertension	To request a change in pack size from a pack of 84 tablets to a pack of 42 tablets and an increase of maximum quantity and number of repeats for the existing listings of 0.5 mg, 1 mg, 1.5 mg, and 2 mg. The submission also requests an increase to the maximum number of repeats for the existing listings of 2.5 mg (84 pack size).
RISDIPLAM Powder for oral solution 0.75 mg per 1 mL, 80 mL Evrysdi® Roche Products Pty Ltd (Change to PBS listing)	Spinal muscular atrophy (SMA)	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (written) listing for the treatment of (i) adults diagnosed with 5q SMA with symptom onset prior to 19 years of age, (ii) patients with confirmed genetic diagnosis of SMA (SMA1 deletion or mutation) who have a SMN2 gene copy number of 1 or 2, and (iii) patients with confirmed genetic diagnosis of SMA (SMA1 deletion or mutation) who have a SMN2 gene copy number of 3.

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RISPERIDONE Powder for I.M. injection 75 mg (modified release) with 0.383 mL diluent in pre-filled syringe Powder for I.M. injection 100 mg (modified release) with 0.49 mL diluent in pre-filled syringe Okedi® Maxx Pharma Pty Ltd (New PBS listing) To be considered at a future PBAC meeting	Schizophrenia	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of schizophrenia.
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 (Telephone/electronic) listing for the treatment of severe established osteoporosis.

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TEBENTAFUSP Solution concentrate for I.V. infusion 100 mcg in 0.5 mL vial Kimmtrak® Synevi Pty Limited (New PBS listing)	Advanced (unresectable or metastatic) human leukocyte antigen (HLA)-A*02:01-positive uveal melanoma	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (telephone/online) listing for the treatment of HLA-A*02:01-positive adult patients with advanced (unresectable or metastatic) uveal melanoma.
TICAGRELOR Tablet, 90 mg Brilinta® AstraZeneca Pty Ltd (Change to PBS listing)	Acute coronary syndrome	To request a change to the restriction level of the existing listing from Authority Required (STREAMLINED) to an unrestricted benefit.
TILDRAKIZUMAB Injection 100 mg in 1 mL single use pre-filled syringe Ilumya® Sun Pharma ANZ Pty Ltd (Change to PBS listing)	Severe chronic plaque psoriasis	To request adding a grandfathering restriction to allow eligible patients enrolled in two tildrakizumab clinical trials to transition to PBS-subsidised tildrakizumab after completing the clinical trials.

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TOFACITINIB Tablet 5 mg Xeljanz® Pfizer Australia Pty Ltd (Change to PBS listing)	Ankylosing spondylitis	To request a General Schedule Authority Required (written) listing for the treatment of ankylosing spondylitis.
TOFACITINIB Tablet 5 mg Oral liquid 1 mg per mL, 240 mL Xeljanz® Pfizer Australia Pty Ltd (New PBS listing)	Juvenile idiopathic arthritis	To request a General Schedule Authority Required (written) listing for the treatment of severe active juvenile idiopathic arthritis.

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ELEXACAFTOR WITH TEZACAFTOR AND WITH IVACAFTOR, AND IVACAFTOR Pack containing 56 tablets elexacaftor 100 mg with tezacaftor 50 mg and with ivacaftor 75 mg and 28 tablets ivacaftor 150 mg Pack containing 56 tablets elexacaftor 50 mg with tezacaftor 25 mg and with ivacaftor 37.5 mg and 28 tablets ivacaftor 75 mg Trikafta® VERTEX PHARMACEUTICALS (AUSTRALIA) PTY. LTD. (New PBS listing)	Cystic fibrosis	To request reconsideration of the financial estimates for Trikafta for the treatment of cystic fibrosis in patients who are aged 6 to 11 years and who have at least one F508del mutation on the cystic fibrosis transmembrane conductance regulator (CFTR) gene.
UPADACITINIB Tablet 15 mg Tablet 30 mg Tablet 45 mg Rinvoq® Abbvie Pty Ltd (Change to PBS listing) To be considered at a future PBAC meeting	Crohn disease	To request a General Schedule Authority Required (written) listing for the treatment of severe Crohn disease.

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URSODEOXYCHOLIC ACID Capsule 250 mg Tablet 500 mg Ursofalk® Dr Falk Pharma Australia Pty Ltd (Change to PBS listing)	Primary biliary cholangitis	To request an increase to the number of repeats for the treatment of primary biliary cholangitis.
VARICELLA ZOSTER VIRUS RECOMBINANT VACCINE Injection [1 vial] & adjuvant substance diluent [0.5 mL vial] Shingrix® GlaxoSmithKline Australia Pty Ltd (New PBS listing)	Prevention of herpes zoster and post-herpetic neuralgia	Resubmission to request a National Immunisation Program listing for the prevention of herpes zoster and post-herpetic neuralgia in: • adults 65 years of age with ongoing catch-up for adults over 65 years of age. • Aboriginal and Torres Strait Islander adults 50 years of age with ongoing catch-up for adults over 50 years of age.
ZANUBRUTINIB Capsule 80 mg Brukinsa® Beigene Aus Pty Ltd (Change to PBS listing)	Chronic lymphocytic leukaemia (CLL)/Small lymphocytic leukaemia (SLL)	To request a General Schedule Authority Required (Telephone/Streamlined) listing for the treatment of treatment naive CLL/SLL.

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

Closing date for consumer comments 25 January 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.)
ZANUBRUTINIB Capsule 80 mg Brukinsa® Beigene Aus Pty Ltd (Change to PBS listing)	Chronic lymphocytic leukaemia (CLL)/Small lymphocytic leukaemia (SLL)	To request a General Schedule Authority Required (Telephone/Streamlined) listing for the treatment of relapsed or refractory CLL/SLL considered unsuitable for treatment or retreatment with a purine analogue.
ARIPIPRAZOLE Powder for injection 400 mg (as monohydrate) with diluent pre-filled dual chamber syringe Abilify Maintena® Lundbeck Australia Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Schizophrenia	

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
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Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)	**Drug Type and Use** (What is the drug used to treat?)	**Listing requested by Sponsor / Purpose of Submission** (Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased.)
AVELUMAB Solution concentrate for I.V. infusion 200 mg in 10 mL Bavencio® Merck Healthcare Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Stage IV clear cell variant renal cell carcinoma	
IBRUTINIB Capsule 140 mg Imbruvica® Janssen-Cilag Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Chronic lymphocytic leukaemia (CLL)/ Small lymphocytic leukaemia (SLL)	

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MENINGOCOCCAL POLYSACCHARIDE SEROGROUPS A, C, W-135 AND Y CONJUGATE VACCINE Injection 0.5 mL MenQuadfi® Sanofi-Aventis Australia Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Prevention of meningococcal disease	
PANCREATIC EXTRACT Capsule (containing enteric coated minimicrospheres) providing not less than 20,000 BP units of lipase activity Creon® Mylan Health Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Cystic fibrosis and unrestricted benefit	

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EVOLOCUMAB All strengths Repatha® Amgen Australia Pty Ltd (Sub-committee report DUSC Analysis)	Hypercholesterolaemia	To compare utilisation of evolocumab across all listed indications.
IMPACT OF REGULATORY REFORMS ON UTILISATION OF OPIOIDS All brands and strengths Various sponsors (Sub-committee report DUSC Analysis)	Opioid medications for the relief of pain	To examine the impact of the 1 June 2020 regulatory reforms and associated PBS listing changes for opioid analgesics.

Version 4
Items added or amended

1. HYALURONIC ACID WITH POLYETHYLENE GLYCOL 400 WITH PROPYLENE GLYCOL WITH HYDROXYPROPYL GUAR (Systane® Hydration) – drug name and form for item amended
2. UPADACITINIB (Rinvoq®) – to be considered at a future PBAC meeting
3. RISPERIDONE (Okedi®) – to be considered at a future PBAC meeting
4. ELEXACAFTOR WITH TEZACAFTOR AND WITH IVACAFTOR, AND IVACAFTOR (Trikafta®) – added

Items added or amended previously

1. AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS (EleCare® LCP) – drug use for item amended
2. NIRAPARIB (Zejula®) – purpose of submission for item amended
3. NIVOLUMAB (Opdivo®) for NSCLC – form for item amended
4. VARICELLA ZOSTER VIRUS RECOMBINANT VACCINE (Shingrix®) – purpose of submission for item amended

Closing date for consumer comments 25 January 2023

5. Addition of ARIPIPRAZOLE (Abilify Maintena®), AVELUMAB (Bavencio®), IBRUTINIB (Imbruvica®), MENINGOCOCCAL POLYSACCHARIDE SEROGROUPS A, C, W-135 AND Y CONJUGATE VACCINE (MenQuadfi®) and PANCREATIC EXTRACT (Creon®) – review of PBAC recommendations not accepted by applicants
6. Sub-committee report (DUSC Analysis): EVOLOCUMAB (Repatha®) – added
7. Sub-committee report (DUSC Analysis): IMPACT OF REGULATORY REFORMS ON UTILISATION OF OPIOIDS – added
8. PATIROMER (Veltassa®) – added
9. BIMEKIZUMAB (Bimzelx®) – form for item amended
10. FOSNETUPITANT (AS CHLORIDE HYDROCHLORIDE)/PALONOSETRON (AS HYDROCHLORIDE) (Akynzeo®IV) – strength for item amended
11. GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS (Camino Pro® Bettermilk, PKU Glytactin RTD 15) – form and purpose of submission for item amended
12. LAROTRECTINIB (Vitrakvi®) – withdrawn
13. RIOCIGUAT (Adempas®) – withdrawn
14. RISPERIDONE (Okedi®) – form for item amended