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

Closing date for consumer comments 25 September 2024

The PBAC agenda primarily consists of applications relating to the new listing of a drug or vaccine on the Pharmaceutical Benefits Scheme (PBS) or the National Immunisation Program (NIP).

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 listing applications
6 Requests for changes to listings
7 Resubmissions
8 Pricing Matters
9 Matters relating to PBS review
10 Subcommittee and Working Party reports
11 Other business
12 Correspondence
13 Further information
14 Late papers
15 Tabled papers
16 Delistings
17 Positive recommendations not accepted by applicants after 2 years

Consumers will have the opportunity to provide comments on new drug submissions (item 5), changes to listings (item 6) and resubmissions (item 7). In many circumstances, consumers will be able to comment on items in other sections of the agenda. The submissions for which input is sought will be listed in alphabetical order by drug name. There is no provision for consumer comments to the PBAC on agenda item 8 which relates to pricing matters.

Pharmaceutical benefits listed in the Schedule fall into three broad categories:
Unrestricted benefits – have no restrictions on their therapeutic uses;
Restricted benefits – can only be prescribed for specific therapeutic uses (noted as Restricted benefit); and
Authority required benefits – Authority required benefits fall into two categories:

- *Authority required benefits* require prior approval from Services Australia or the DVA (noted as Authority required)
- *Authority required (STREAMLINED) benefits* do not require prior approval from Services Australia or the DVA but require the recording of a streamlined authority code (noted as Authority required (STREAMLINED)).

Initial submissions are categorised broadly as:

- *Category 1 or 2:* Submissions to list new medicines on the Schedule of Pharmaceutical Benefits or to make substantial changes to current listings are generally classified as Category 1 or 2 submissions. These submissions require presentation of an economic evaluation.

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- *Category 3 or 4:* Submissions that relate to new forms of previously listed products and changes to the conditions of use e.g. change in maximum quantity/repeats or clarifying the wording of a restriction (while not altering the intended use) are considered to be Category 3 or 4 submissions. These submissions do not usually require the presentation of an economic evaluation.

Resubmissions are categorised broadly as Standard Re-entry Pathway, Early Resolution Pathway, Early Re-entry Pathway or Facilitated Resolution Pathway. Submission categories and resubmission pathways are outlined in the Procedure Guidance.

The PBAC meeting agenda will be published in week 3 – and updated in week 8 (to include early pathway resubmissions, and items for review under the process for reviewing positive PBS-listing recommendations not accepted by applicants) in each PBAC cycle as per PBS Calendar.

Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)	**Drug Type and Use** (What is the drug used to treat?)	**Listing requested by Sponsor / Purpose of Submission** (Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased.)
ABROCITINIB Tablet 50 mg Tablet 100 mg Tablet 200 mg Cibinqo® PFIZER AUSTRALIA PTY LTD (New PBS listing)	Severe atopic dermatitis	To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of severe atopic dermatitis.

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AFLIBERCEPT Solution for intravitreal injection 11.34 mg in 100 microlitres (114.3 mg per mL) pre-filled syringe Eylea® BAYER AUSTRALIA LTD (New PBS listing)	Diabetic macular oedema (DMO)	To request a General Schedule Authority Required (Written) listing of a new form for the initial treatment and an Authority Required (STREAMLINED) listing for the continuing treatment of DMO.
AFLIBERCEPT Solution for intravitreal injection 11.34 mg in 100 microlitres (114.3 mg per mL) pre-filled syringe Eylea® BAYER AUSTRALIA LTD (New PBS listing)	Subfoveal choroidal neovascularisation (CNV) secondary to age-related macular degeneration (AMD)	To request a General Schedule Authority Required (Written) listing of a new form for the initial treatment and an Authority Required (STREAMLINED) listing for the continuing treatment of subfoveal CNV due to AMD.

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AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS AND MINERALS WITHOUT PHENYLALANINE Tablets (modified release), 54 g protein per 100 g, 100 g, pack of 6 (PKU Easy Microtabs Plus) PKU Easy Microtabs Plus ORPHARMA PTY LTD (New PBS listing)	Phenylketonuria (PKU)	To request a General Schedule Restricted Benefit listing for the dietary management of phenylketonuria.
AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES Oral powder 400 g (Essential Care Jr) Essential Care Jr CORTEX HEALTH PTY LTD (New PBS listing)	Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae Severe intestinal malabsorption including short bowel syndrome Eosinophilic oesophagitis Cows' milk protein enteropathy Severe cows' milk protein enteropathy with failure to thrive Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein Cows' milk anaphylaxis	To request a General Schedule Authority Required (Telephone/Online) listing of a new pack size with new formulation for the same indications as the current listing.

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AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN Sachets containing oral powder 12.5 g, pack of 30 (GA explore5) GA explore5™ VITAFLO AUSTRALIA PTY LIMITED (New PBS listing)	Glutaric aciduria type 1 Pyridoxine dependent epilepsy	To request a General Schedule Restricted Benefit listing for the dietary management of proven glutaric aciduria type 1 and pyridoxine dependent epilepsy.
AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINE Sachets containing oral powder 12.5 g, pack of 30 (MMA/PA explore5) MMA/PA explore5™ VITAFLO AUSTRALIA PTY LIMITED (New PBS listing)	Methylmalonic acidaemia Propionic acidaemia	To request a General Schedule Restricted Benefit listing for the dietary management of methylmalonic acidaemia and propionic acidaemia.

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AMIVANTAMAB Solution concentrate for I.V. infusion 350 mg in 7 mL Rybrevant® JANSSEN-CILAG PTY LTD (New PBS listing)	Non-small cell lung cancer (NSCLC)	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for the treatment of epidermal growth factor receptor exon 20 insertion mutation-positive locally advanced or metastatic (Stage IIIb-IV) NSCLC in treatment naive patients.
BUDESONIDE Suppository 4 mg Budenofalk® DR FALK PHARMA AUSTRALIA PTY LTD (New PBS listing)	Ulcerative colitis	To request a General Schedule Unrestricted Benefit listing of a new form for the short-term treatment of mild to moderate ulcerative colitis limited to the rectum.

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CAPIVASERTIB Tablet 160 mg Tablet 200 mg Truqap® ASTRAZENECA PTY LTD (New PBS listing)	Hormone receptor-positive (HR+) human epidermal growth factor receptor 2-negative (HER2-) locally advanced (unresectable) or metastatic breast cancer	To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of HR+/HER2- locally advanced unresectable or metastatic breast cancer with evidence of a serine/threonine protein kinase (AKT) pathway alteration, following recurrence or progression on or after endocrine therapy.
CLOBETASOL Cream containing clobetasol propionate 500 micrograms per g, 30 g Ointment containing clobetasol propionate 500 micrograms per g, 30 g Xobet® ARROTEX PHARMACEUTICALS PTY LTD (New PBS listing)	Corticosteroid responsive dermatoses	To request a General Schedule Restricted Benefit listing for the treatment of corticosteroid responsive dermatoses.

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DENOSUMAB Injection 60 mg in 1 mL pre-filled syringe Jubbonti® Injection 120 mg in 1.7 mL Wyost® SANDOZ PTY LTD (New PBS listing)	Osteoporosis Giant cell tumour of bone Bone metastases	To request General Schedule Authority Required (STREAMLINED) listings of denosumab biosimilars under the same conditions as their respective reference biologics.
DROSPIRENONE Pack containing 24 tablets 4 mg and 4 inert tablets Slinda® BESINS HEALTHCARE AUSTRALIA PTY LTD (New PBS listing)	Contraception	To request a General Schedule unrestricted benefit listing.

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DURVALUMAB Solution concentrate for I.V. infusion 120 mg in 2.4 mL Solution concentrate for I.V. infusion 500 mg in 10 mL Imfinzi® OLAPARIB Tablet 100 mg Tablet 150 mg Lynparza® ASTRAZENECA PTY LTD (Change to existing listing)	Advanced, metastatic or recurrent endometrial cancer	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing of durvalumab in combination with platinum-based chemotherapy, followed by maintenance treatment with or without olaparib, for the treatment of advanced, metastatic or recurrent endometrial cancer.
ENFORTUMAB VEDOTIN Powder for I.V. infusion 20 mg Powder for I.V. infusion 30 mg Padcev® ASTELLAS PHARMA AUSTRALIA PTY LTD (Change to existing listing)	Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer (la/mUC)	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first line treatment of la/mUC in combination with pembrolizumab.

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ENZALUTAMIDE Capsule 40 mg Xtandi® ASTELLAS PHARMA AUSTRALIA PTY LTD (Change to existing listing)	Non-metastatic hormone-sensitive prostate cancer (m0HSPC)	To request a General Schedule Authority Required (Telephone/Online) for the treatment of m0HSPC with or without concurrent treatment with androgen deprivation therapy.
EPCORITAMAB Solution concentrate for subcutaneous injection 4 mg in 0.8 mL Solution for subcutaneous injection 48 mg in 0.8 mL Epkinly® ABBVIE PTY LTD (New PBS listing)	Relapsed or refractory diffuse large B-cell lymphoma (RR DLBCL)	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of RR DLBCL.

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ERENUMAB Solution for subcutaneous injection 70 mg in 1 mL single dose pre-filled pen Solution for subcutaneous injection 140 mg in 1 mL single dose pre-filled pen Aimovig® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED (New PBS listing)	Chronic migraine	Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the prophylaxis of adults with chronic migraine who have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications.
ESTRADIOL AND PROGESTERONE Pack containing transdermal gel (pump pack) estradiol 750 micrograms (as hemihydrate) per 1.25 g dose, 64 doses and 30 capsules progesterone 100 mg (micronised) Estrogel® Pro BESINS HEALTHCARE AUSTRALIA PTY LTD (New PBS listing)	Menopausal hormone therapy	To request a General Schedule unrestricted benefit listing.

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ESTRADIOL Transdermal gel (pump pack) 750 micrograms (as hemihydrate) per 1.25 g dose, 64 doses Estrogel® BESINS HEALTHCARE AUSTRALIA PTY LTD (New PBS listing)	Menopausal hormone therapy	To request a General Schedule unrestricted benefit listing.
FENFLURAMINE Oral solution 2.2 mg (as hydrochloride) per mL, 360 mL Fintepla® UCB AUSTRALIA PROPRIETARY LIMITED (New PBS listing)	Seizures associated with Dravet Syndrome	To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of seizures associated with Dravet Syndrome.

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FINGOLIMOD Capsule 250 micrograms (as hydrochloride) Capsule 500 micrograms (as hydrochloride) Gilenya® OFATUMUMAB Solution for injection 20 mg in 0.4 mL pre-filled pen Kesimpta® SIPONIMOD Tablet 250 micrograms (as hemifumarate) Tablet 2 mg (as hemifumarate) Mayzent® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED (Change to existing listing)	Multiple sclerosis (MS)	To request an amendment to the listings for the treatment of MS to allow prescribing by nurse practitioners.

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FOLLITROPIN ALFA WITH LUTROPIN ALFA Injection 900 I.U. - 450 I.U. in 1.44 mL multi-dose cartridge Pergoveris® MERCK HEALTHCARE PTY LTD (Change to existing listing)	Stimulation of follicular development	To request an amendment to the existing Section 100 (In Vitro Fertilisation Program) Authority Required (STREAMLINED) listing for the stimulation of follicular development to remove the requirement for titration of separate follicular stimulating hormone and luteinising hormone therapies after at least one cycle of treatment, and to request an increase to the maximum quantity.
FOSLEVODOPA WITH FOSCARBIDOPA Solution for subcutaneous infusion foslevodopa 2400 mg with foscarbidopa 120 mg in 10 mL Vyalev® ABBVIE PTY LTD (New PBS listing)	Advanced Parkinson disease	Resubmission to request General Schedule and Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listings for the treatment of advanced Parkinson disease with severe disabling motor fluctuations not adequately controlled by oral therapy.

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GARADACIMAB Injection 200 mg in 1.2 mL pre-filled pen TBD CSL BEHRING (AUSTRALIA) PTY LTD (New PBS listing)	Hereditary angioedema (HAE)	To request a General Schedule Authority Required (Written) listing for the initial treatment and an Authority Required (Telephone/Online) listing for the continuing treatment of HAE.
GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS Sachets containing oral powder 15 g, 30 (PKU Build 10) PKU Build 10 CORTEX HEALTH PTY LTD (New PBS listing)	Phenylketonuria (PKU)	To request a General Schedule Restricted Benefit listing of a new pack size for the dietary management of phenylketonuria.

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INCLISIRAN Injection 284 mg in 1.5 mL single use pre-filled syringe Leqvio® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED (Change to existing listing)	Non-familial hypercholesterolaemia Familial heterozygous hypercholesterolaemia	To request an amendment to the restriction level from Authority Required (Telephone/Online) to Authority Required (STREAMLINED) for the initial treatment of familial heterozygous hypercholesterolaemia and non-familial hypercholesterolaemia.
INCLISIRAN Injection 284 mg in 1.5 mL single use pre-filled syringe Leqvio® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED (Change to existing listing)	Non-familial hypercholesterolaemia Familial heterozygous hypercholesterolaemia	To request an amendment to the listing for the treatment of familial heterozygous hypercholesterolaemia and non-familial hypercholesterolaemia to allow prescribing by nurse practitioners.

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INCOBOTULINUMTOXINA Lyophilised powder for injection 100 units Xeomin® MERZ AUSTRALIA PTY LTD (Change to existing listing)	Chronic sialorrhea	To request a Section 100 (Botulinum Toxin Program) Authority Required (STREAMLINED) listing for the treatment of chronic sialorrhea due to neurological disorders.
INCOBOTULINUMTOXINA Lyophilised powder for injection 100 units Xeomin® MERZ AUSTRALIA PTY LTD (Change to existing listing) WITHDRAWN	Moderate to severe spasticity of the upper limb Dynamic equinus foot deformity	To request a Section 100 (Botulinum Toxin Program) Authority Required (STREAMLINED) listing for the treatment of moderate to severe spasticity of the upper limb and dynamic equinus foot deformity in patients with cerebral palsy aged 2 to 17 years.

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IRINOTECAN Solution for I.V. infusion containing nanoliposomal irinotecan (as sucrosofate) 43 mg in 10 mL Onivyde® SERVIER LABORATORIES (AUST.) PTY. LTD. (New PBS listing)	Metastatic pancreatic adenocarcinoma (mPAC)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing, for use in combination with oxaliplatin, 5-fluorouracil and folinic acid, for the first-line treatment of mPAC.
IVOSIDENIB Tablet 250 mg Tibsovo® SERVIER LABORATORIES (AUST.) PTY. LTD. (New PBS listing)	Bile duct cancer (cholangiocarcinoma)	Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma who have previously progressed on chemotherapy and have a confirmed *IDH1* mutation.

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LANADELUMAB Injection 150 mg in 1 mL single use pre-filled syringe Takhzyro® TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD. (New PBS listing)	Hereditary angioedema (HAE)	To request a General Schedule Authority Required (Written) listing of a new form for the treatment of HAE Types 1 or 2 in patients aged 2 to 11 years.

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LEUPRORELIN Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 7.5 mg, injection set Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 22.5 mg, injection set Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 30 mg, injection set Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 45 mg, injection set Eligard® MUNDIPHARMA PTY LIMITED (Change to existing listing)	Central precocious puberty Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate	To request a modified injection device for the existing listing.
MACITENTAN WITH TADALAFIL Tablet containing macitentan 10 mg with tadalafil 40 mg Opsynvi® JANSSEN-CILAG PTY LTD (New PBS listing)	Pulmonary arterial hypertension (PAH)	To request a Section 100 (Highly Specialised Drug Program) Authority Required (Written) listing for the continuing treatment of PAH in patients who are on stable doses of macitentan and tadalafil as combination therapy.

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MARIBAVIR Tablet 200 mg Livtencity® TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD. (New PBS listing)	Post-transplant cytomegalovirus (CMV)	Resubmission 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.
MOMELOTINIB Tablet 100 mg (as dihydrochloride monohydrate) Tablet 150 mg (as dihydrochloride monohydrate) Tablet 200 mg (as dihydrochloride monohydrate) Omjjara® GLAXOSMITHKLINE AUSTRALIA PTY LTD (New PBS listing)	Myelofibrosis with moderate to severe anaemia	To request a General Schedule Authority Required (Telephone/Online) listing for initial treatment and an Authority Required (STREAMLINED) listing for continuing treatment of intermediate or high-risk primary myelofibrosis, post-polycythaemia vera myelofibrosis or post-essential thrombocythaemia myelofibrosis in patients with moderate to severe anaemia and who are Janus kinase (JAK) inhibitor naïve or have been treated with ruxolitinib.

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NINTEDANIB Capsule 100 mg Capsule 150 mg Ofev® BOEHRINGER INGELHEIM PTY LTD (Change to existing listing)	Idiopathic pulmonary fibrosis (IPF) Progressive fibrosing Interstitial lung disease (PF-ILD)	To request the PBAC consider the combined utilisation and financial estimates for the IPF and PF-ILD indications of nintedanib listed on the PBS.
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) 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 perioperative treatment of NSCLC.

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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 existing listing)	Urothelial carcinoma (UC)	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for the first-line treatment of cisplatin-eligible adult patients with unresectable or metastatic UC.
OLAPARIB Tablet 100 mg Tablet 150 mg Lynparza® ASTRAZENECA PTY LTD (New PBS listing)	Metastatic castration-resistant prostate cancer (mCRPC)	Resubmission 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.

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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.)
PALOVAROTENE Capsule 1 mg Capsule 1.5 mg Capsule 2.5 mg Capsule 5 mg Capsule 10 mg Sohonos® IPSEN PTY LTD (New PBS listing)	Fibrodysplasia Ossificans Progressiva (FOP)	To request a General Schedule Authority Required (Written) listing for chronic treatment of FOP and an Authority Required (STREAMLINED) listing for flare-up treatment of FOP.
PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® MERCK SHARP & DOHME (AUSTRALIA) PTY LTD (Change to existing listing)	Renal cell carcinoma (RCC)	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the adjuvant treatment of clear cell RCC at intermediate-high or high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions.

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PNEUMOCOCCAL (CONJUGATE, 21-VALENT) VACCINE Injection (0.5 mL) Capvaxive® MERCK SHARP & DOHME (AUSTRALIA) PTY LTD (New NIP listing) WITHDRAWN	Prevention of pneumococcal disease	To request a National Immunisation Program listing for the prevention of pneumococcal disease in adults.
PROGESTERONE Capsule 100 mg Prometrium® BESINS HEALTHCARE AUSTRALIA PTY LTD (New PBS listing)	Menopausal hormone therapy	To request a General Schedule unrestricted benefit listing.

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RAVULIZUMAB Solution concentrate for I.V. infusion 300 mg in 3 mL Solution concentrate for I.V. infusion 1,100 mg in 11 mL Ultomiris® ALEXION PHARMACEUTICALS AUSTRALASIA PTY LTD (Change to existing listing)	Neuromyelitis Optica Spectrum Disorder (NMOSD)	To request a Section 100 (Highly Specialised Drug Program) Authority Required (Written) listing for the treatment of adult patients with NMOSD.
RELUGOLIX WITH ESTRADIOL AND WITH NORETHISTERONE ACETATE Tablet containing relugolix 40 mg with estradiol (as hemihydrate) 1 mg and with norethisterone acetate 0.5 mg Ryeqo® GEDEON RICHTER AUSTRALIA PTY LTD (New PBS listing)	Endometriosis	To request reconsideration of the utilisation and financial estimates of the General Schedule Authority Required (STREAMLINED) listing for the treatment of moderate to severe pain associated with endometriosis.

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RESPIRATORY SYNCYTIAL VIRUS VACCINE Injection (0.5 mL) Abrysvo® PFIZER AUSTRALIA PTY LTD (New NIP listing)	Respiratory syncytial virus (RSV)	To request a National Immunisation Program listing for the prevention of RSV lower respiratory tract disease in individuals 60 years of age and above who meet certain criteria.
RIBOCICLIB Tablet 200 mg Kisqali® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED (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 adjuvant treatment of HR+/HER2- lymph node positive, invasive, resected early breast cancer at high risk of disease recurrence.
RIVAROXABAN Tablet 2.5 mg Tablet 10 mg Xarelto® ALPHAPHARM PTY LTD (New PBS listing)	Prevention of venous thromboembolism Chronic stable atherosclerotic disease	To request General Schedule Authority Required (STREAMLINED) listings of new pack sizes with amended maximum quantities and number of repeats for the treatment of chronic stable atherosclerotic disease and the prevention of recurrent venous thromboembolism.

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SACUBITRIL WITH VALSARTAN Tablet containing sacubitril 24.3 mg with valsartan 25.7 mg Tablet containing sacubitril 48.6 mg with valsartan 51.4 mg Tablet containing sacubitril 97.2 mg with valsartan 102.8 mg Entresto® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED (Change to existing listing)	Chronic heart failure	To request an amendment to the General Schedule Authority Required (STREAMLINED) listings for the treatment of chronic heart failure to allow treatment initiation by nurse practitioners.
SEMAGLUTIDE Solution for injection 2 mg in 3 mL pre-filled pen Ozempic® NOVO NORDISK PHARMACEUTICALS PTY. LIMITED (New PBS listing)	Diabetes mellitus type 2 (T2DM)	To request a General Schedule Authority Required (Telephone/Online) listing of a new strength for the initial treatment and an Authority Required (STREAMLINED) listing for the continuing treatment of T2DM.

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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.)
TIOTROPIUM WITH OLODATEROL Solution for oral inhalation containing tiotropium 2.5 micrograms (as bromide monohydrate) with olodaterol 2.5 micrograms (as hydrochloride) per dose, 60 doses, pack of 2 Spiolto® Respimat® BOEHRINGER INGELHEIM PTY LTD (New PBS listing)	Chronic obstructive pulmonary disease (COPD)	To request listing of a new pack size for 60-day prescribing for the treatment of COPD.
TIOTROPIUM Solution for oral inhalation 2.5 micrograms (as bromide monohydrate) per actuation (2 x 60 actuations), pack of 2 Spiriva® Respimat® BOEHRINGER INGELHEIM PTY LTD (New PBS listing)	Severe asthma Bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease (COPD)	To request listing of a new pack size for 60-day prescribing for the treatment of severe asthma and for bronchospasm and dyspnoea associated with COPD.

TIRZEPATIDE Solution for injection 2.5 mg in 0.5 mL vial/pre-filled pen Solution for injection 5 mg in 0.5 mL vial/pre-filled pen Solution for injection 7.5 mg in 0.5 mL vial/pre-filled pen Solution for injection 10 mg in 0.5 mL vial/pre-filled pen Solution for injection 12.5 mg in 0.5 mL vial/pre-filled pen Solution for injection 15 mg in 0.5 mL vial/pre-filled pen Mounjaro® Injection 4.17 milligrams per mL (2.5 mg per dose) in multi-dose pre-filled pen, 4 doses Injection 8.33 milligrams per mL (5 mg per dose) in multi-dose pre-filled pen, 4 doses Injection 12.5 milligrams per mL (7.5 mg per dose) in multi-dose pre-filled pen, 4 doses Injection 16.67 milligrams per mL (10 mg per dose) in multi-dose pre-filled pen, 4 doses Injection 20.83 milligrams per mL (12.5 mg per dose) in multi-dose pre-filled pen, 4 doses Injection 25 milligrams per mL (15 mg per dose) in multi-dose pre-filled pen, 4 doses Mounjaro® KwikPen® ELI LILLY AUSTRALIA PTY LTD (New PBS listing)	Diabetes mellitus type 2 (T2DM)	Resubmission to request a General Schedule Authority Required (Written) listing as dual therapy in combination with metformin for the treatment of adult patients with inadequately controlled T2DM who (i) have comorbid severe obesity or (ii) identify as Aboriginal and Torres Strait Islander.

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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.)
TISLELIZUMAB Solution concentrate for I.V. infusion 100 mg in 10 mL Tevimbra® BEIGENE AUS PTY LTD (New PBS listing)	Oesophageal squamous cell carcinoma (OSCC)	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first line treatment of patients with unresectable advanced, recurrent, or metastatic OSCC.
TRIGLYCERIDES, LONG CHAIN WITH GLUCOSE POLYMER Oral liquid 1 L, 6 (ProZero) ProZero® VITAFLO AUSTRALIA PTY LIMITED (Change to existing listing)	Proven inborn errors of protein metabolism	To request an amendment to the restriction level from Restricted Benefit to Authority Required (STREAMLINED) for the treatment of proven inborn errors of protein metabolism. The submission also requested amendments to the clinical criteria.

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USTEKINUMAB Injection 45 mg in 0.5 mL single use pre-filled syringe Injection 90 mg in 1 mL single use pre-filled syringe Solution for I.V. infusion 130 mg in 26 mL Steqeyma® CELLTRION HEALTHCARE AUSTRALIA PTY LTD (New PBS listing)	Severe chronic plaque psoriasis Severe psoriatic arthritis Severe Crohn disease Complex refractory fistulising Crohn disease	To request General Schedule and Section 100 (Highly Specialised Drugs Program) listings of an ustekinumab biosimilar for the treatment of severe chronic plaque psoriasis, severe psoriatic arthritis, severe Crohn disease, and complex refractory fistulising Crohn disease.
VUTRISIRAN Injection 25 mg (as sodium) in 0.5 mL pre-filled syringe Amvuttra® MEDISON PHARMA AUSTRALIA PTY LIMITED (New PBS listing)	Hereditary transthyretin-mediated (hATTR) amyloidosis	To request a General Schedule Authority Required (Written) listing for the treatment of hATTR amyloidosis in adult patients with stage 1 or stage 2 polyneuropathy.

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DASATINIB Tablet 20 mg Tablet 50 mg Tablet 70 mg Tablet 100 mg All Brands NILOTINIB Capsule 150 mg Capsule 200 mg Tasigna® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED (Sub-committee report DUSC analysis)	Chronic myeloid leukaemia (CML)	To assess the utilisation of PBS listed dasatinib and nilotinib for the treatment of CML.
IDELALISIB Tablet 100 mg Tablet 150 mg Zydelig® GILEAD SCIENCES PTY LIMITED (Sub-committee report DUSC analysis)	Refractory follicular B-cell non-Hodgkin lymphoma	To assess the utilisation of PBS listed idelalisib for the treatment of refractory follicular B-cell non-Hodgkin lymphoma.

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MOLNUPIRAVIR Capsule 200 mg Lagevrio® MERCK SHARP & DOHME (AUSTRALIA) PTY LTD (Sub-committee report DUSC analysis)	Severe-acute-respiratory-syndrome coronavirus-2 (SARS-CoV-2) infection	To assess the utilisation of PBS listed molnupiravir for the treatment of SARS-CoV-2 infection.
DUPILUMAB Injection 300 mg in 2 mL single dose autoinjector Injection 200 mg in 1.14 mL single dose autoinjector Dupixent® SANOFI-AVENTIS AUSTRALIA PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Chronic severe atopic dermatitis Uncontrolled severe asthma	To request the PBAC review its November 2022 recommendation that has not yet been accepted by the applicant.

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ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4 Nepexto® ALPHAPHARM PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Rheumatoid arthritis Juvenile idiopathic arthritis Psoriatic arthritis Plaque psoriasis Ankylosing spondylitis	To request the PBAC review its November 2022 recommendation that has not yet been accepted by the applicant.
HYDROCORTISONE Capsule containing granules 0.5 mg Capsule containing granules 1 mg Capsule containing granules 2 mg Capsule containing granules 5 mg Alkindi® CHIESI AUSTRALIA PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Adrenal insufficiency	To request the PBAC review its July 2021 recommendation that has not yet been accepted by the applicant.

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INFLIXIMAB Solution for injection 120 mg in 1 mL pre-filled pen Solution for injection 120 mg in 1 mL pre-filled syringe Remsima® SC CELLTRION HEALTHCARE AUSTRALIA PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Rheumatoid arthritis	To request the PBAC review its November 2022 recommendation that has not yet been accepted by the applicant.
INSULIN ASPART Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5 Truvelog® Injections (human analogue), prefilled pen, 100 units per mL, 3 mL, 5 Truvelog® Solostar SANOFI-AVENTIS AUSTRALIA PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Diabetes mellitus	To request the PBAC review its November 2021 recommendation that has not yet been accepted by the applicant.

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RISANKIZUMAB Solution concentrate for I.V. infusion 600 mg in 10 mL Injection 360 mg in 2.4 mL in prefilled cartridge Skyrizi® ABBVIE PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Crohn disease	To request the PBAC review its November 2022 recommendation that has not yet been accepted by the applicant.
Review of PBS items for Nurse Practitioner prescribing subject to a 'Continuing Therapy Only' administrative note Various forms and strengths Various brands Various sponsors (Other matters)	Various	To request the PBAC consider a list of medicines with a Continuing Therapy Only (CTO) administrative note for nurse practitioner prescribing, and seek PBAC advice on whether the CTO note continues to be appropriate for specific listings.

Version 6
Items added or amended
1. PNEUMOCOCCAL (CONJUGATE, 21-VALENT) VACCINE (Capvaxive®) – Withdrawn
2. NIVOLUMAB (Opdivo®) non-small cell lung cancer – To be considered at a future PBAC Meeting

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Items added or amended previously

3. INCOBOTULINUMTOXINA (Xeomin®) – Withdrawn
4. NIVOLUMAB (Opdivo®) non-small cell lung cancer – Form(s) amended
5. NIVOLUMAB (Opdivo®) urothelial carcinoma – Form(s) amended
6. RIVAROXABAN (Xarelto®) – Sponsor amended
7. CAPIVASERTIB (Truqap®) – Purpose of submission amended
8. FOSLEVODOPA WITH FOSCARBIDOPA (Vyalev®) – Added
9. GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS (PKU Build 10) – Form amended
10. IVOSIDENIB (Tibsovo®) – Added
11. SEMAGLUTIDE (Ozempic®) – Purpose of submission amended
12. TIRZEPATIDE (Mounjaro®; Mounjaro® KwikPen®) – Forms, strength, trade name and purpose of submission amended
13. DUPILUMAB (Dupixent®) – Review of positive PBAC recommendations not accepted by applicants – Added
14. ETANERCEPT (Nepexto®) – Review of positive PBAC recommendations not accepted by applicants – Added
15. HYDROCORTISONE (Alkindi®) – Review of positive PBAC recommendations not accepted by applicants – Added
16. INFLIXIMAB (Remsima® SC) – Review of positive PBAC recommendations not accepted by applicants – Added
17. INSULIN ASPART (Truvelog®; Truvelog® Solostar) – Review of positive PBAC recommendations not accepted by applicants – Added
18. RISANKIZUMAB (Skyrizi®) – Review of positive PBAC recommendations not accepted by applicants – Added
19. Review of PBS items for Nurse Practitioner prescribing subject to a 'Continuing Therapy Only' administrative note (Various brands) – Added
20. ERENUMAB (Aimovig®) – Purpose of submission amended
21. FENFLURAMINE (Fintepla®) – Drug type and use and purpose of submission amended