

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
JULY 2020 PBAC MEETING**

Closing date for consumer comments is 10 June 2020

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

The PBAC agenda consists of the following:

- 1 Minutes of Previous Meeting**
- 2 Chairman's report (verbal)**
- 3 Matters arising from the minutes**
- 4 Matters arising/outstanding**
- 5 New drug applications**
- 6 Requests for changes to listings**
- 7 Resubmissions**
- 8 Pricing Matters**
- 9 Matters relating to PBS review**
- 10 Subcommittee and Working Party reports**
- 11 Other business**
- 12 Correspondence**
- 13 Further information**
- 14 Late papers**
- 15 Tabled papers**

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

Pharmaceutical benefits listed in the Schedule fall into three broad categories:

Unrestricted benefits – have no restrictions on their therapeutic uses;

Restricted benefits – can only be prescribed for specific therapeutic uses (noted as Restricted benefit); and

Authority required benefits – Authority required benefits fall into two categories:

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

Submissions are categorised broadly as major or minor:

- *Major:* Submissions to list new medicines on the Schedule of Pharmaceutical Benefits or to make substantial changes to current listings are generally classified as major submissions. Major submissions require presentation of an economic evaluation.
- *Minor:* 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 minor submissions. Minor submissions do not usually require the presentation of an economic evaluation.

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New listing (Major Submission)	ACALABRUTINIB Capsule 100 mg Calquence® AstraZeneca Pty Ltd	Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)	To request an Authority Required listing for the treatment of patients (either as monotherapy or in combination with obinutuzumab) with previously untreated CLL or SLL considered unsuitable for treatment with a purine analogue. A second request was for use only in the subgroup of patients with a 17p deletion.
Change to listing (Minor Submission)	ADALIMUMAB Injection 40 mg in 0.8 mL pre-filled syringe Injection 40 mg in 0.8 mL single dose autoinjector Hadlima® Merck, Sharp & Dohme (Australia) Pty Ltd	Severe active rheumatoid arthritis; Severe psoriatic arthritis; Ankylosing spondylitis; Severe chronic plaque psoriasis; Juvenile idiopathic arthritis; Severe crohn's disease; Refractory fistulising crohn's disease; moderate to severe hidradenitis suppurativa	To request an extension to the currently approved PBS listing of Hadlima to include all indications for which Humira is currently PBS listed.

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Change to listing (Minor Submission)	<p>AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE</p> <p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE</p> <p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN</p> <p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE , THREONINE AND VALINE AND LOW IN ISOLEUCINE</p> <p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE</p> <p>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE</p> <p>Oral powder 400 g</p> <p>Anamix Infant® Formulas</p> <p>Nutricia Australia Pty Ltd</p>	<p>Phenylketonuria Tyrosinaemia Glutaric Aciduria Type 1 Methylmalonic acidaemia and Propionic acidaemia Proven pyridoxine non-responsive homocystinuria Proven maple syrup urine disease</p>	To request a change to the formulation of Anamix Infant products.

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New listing (Minor Submission)	AMINO ACID FORMULA WITH CARBOHYDRATE, VITAMINS, MINERALS AND TRACE ELEMENTS WITHOUT PHENYLALANINE, SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID Sachets containing oral powder 33 g, 30 PKU Synergy® Nutricia Australia Pty Ltd	Phenylketonuria	Resubmission to request a Restricted Benefit listing for the dietary management of phenylketonuria
New listing (Minor Submission)	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE Sachets containing oral powder 28 g, 30 HCU Lophlex® Nutricia Australia Pty Ltd	Pyridoxine non-responsive homocystinuria	To request an Authority Required PBS listing of HCU Lophlex for the dietary management of homocystinuria.
New listing (Minor Submission)	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE Sachets containing oral powder 28 g, 30 TYR Lophlex® Nutricia Australia Pty Ltd	Tyrosinaemia	To request an Authority Required PBS listing of TYR Lophlex for the dietary management of tyrosinaemia.

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New listing (Minor Submission)	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE Sachets containing oral powder 28 g, 30 MSUD Lophlex® Nutricia Australia Pty Ltd	Maple Syrup Urine Disease	To request the Authority Required PBS listing of MSUD Lophlex for the dietary management of Maple Syrup Urine Disease.
New listing (Minor Submission)	APREMILAST Tablet 30mg Pack containing 4 tablets of 10 mg, 4 tablets of 20 mg and 19 tablets of 30 mg Otezla® Amgen Australia Pty Ltd	Plaque psoriasis	Resubmission to request the Authority Required (STREAMLINED) listing of apremilast for the treatment of plaque psoriasis.
Change to listing (Minor Submission)	ARMODAFINIL & MODAFINIL modafinil Tablet 100 mg armodafinil Tablet 50 mg Tablet 150 mg Tablet 250 mg Various brands Australasian Sleep Association	Narcolepsy	To request that the PBS listings for armodafinil and modafinil be changed to first line treatment for narcolepsy in line with current clinical guidelines.

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Change to listing (Major Submission)	<p>ATEZOLIZUMAB + BEVACIZUMAB</p> <p>Atezolizumab: Solution concentrate for I.V. infusion 1200 mg in 20 mL, Solution concentrate for I.V. infusion 840 mg in 14 mL</p> <p>Tecentriq®</p> <p>Bevacizumab: Solution for I.V. infusion 100 mg in 4 mL, Solution for I.V. infusion 400 mg in 16 mL</p> <p>Avastin®</p> <p>Roche Products Pty Ltd</p>	Hepatocellular carcinoma (HCC)	To request Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listings for the treatment of patients with advanced (unresectable) locally advanced or metastatic Barcelona Clinic Liver Cancer Stage B or Stage C HCC who have not received prior systemic therapy.
New listing (Major Submission)	<p>BECLOMETASONE DIPROPIONATE + FORMOTEROL FUMARATE DIHYDRATE</p> <p>Powder for oral inhalation in breath actuated device containing beclometasone dipropionate 100 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses</p> <p>Fostair®</p> <p>Emerge Health Pty Ltd</p>	Asthma	To request an Authority Required (STREAMLINED) listing for the treatment of patients with asthma.

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New listing (Major Submission)	BELIMUMAB Injection 200 mg in 1 mL pre-filled pen Benlysta® GlaxoSmithKline Australia Pty Ltd	Systemic lupus erythematosus (SLE)	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of patients with highly active autoantibody positive SLE.
New listing (Minor Submission)	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	Advanced International Federation of Gynecology and Obstetrics (FIGO) Stage IIIB, IIIC or Stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer. Advanced carcinoma of cervix. Relapsed or recurrent glioblastoma. Stage IV (metastatic) non-small cell lung cancer (NSCLC). Metastatic colorectal cancer.	To request an Authority Required (STREAMLINED) listing of a new biosimilar bevacizumab under the same conditions as the reference biologic.
New listing (Minor Submission)	BIMATOPROST 300 micrograms per mL, 3mL Vizo-PF Bimatoprost® AFT Pharmaceuticals Pty Ltd	Reduction of elevated intraocular pressure or open angle glaucoma, as first line therapy or monotherapy or as adjunctive therapy to topical beta-blockers.	To request the unrestricted PBS listing for Vizo-PF Bimatoprost for the reduction of elevated intraocular pressure, or open angle glaucoma, as first line therapy or monotherapy or as adjunctive therapy to topical beta-blockers.

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New listing (Minor Submission)	BROLUCIZUMAB Solution for intravitreal injection 19.8 mg in 0.165 mL pre-filled syringe Beovu® Novartis Pharmaceuticals Australia Pty Ltd	Subfoveal choroidal neovascularisation (CNV)	To request the Authority Required PBS listing for the treatment of subfoveal choroidal neovascularisation (CNV).
New listing (Major Submission)	CANNABIDIOL Oral solution, 100 mg per mL, 100 mL Epidyolex® Emerge Health Pty Ltd	Lennox-Gastaut syndrome Dravet syndrome	To request a Section 100 (Highly Specialised Drugs Program - Community Access) Authority Required (STREAMLINED) listing for the adjunctive treatment of seizures in patients with Lennox-Gastaut syndrome or Dravet syndrome in patients aged 2 years or older.
New listing (Major Submission)	CAPLACIZUMAB Injection set containing 1 vial powder for injection 10 mg and 1 pre-filled syringe solvent 1 mL Cabliivi® Sanofi-Aventis Australia Pty Ltd	Acquired thrombotic thrombocytopenic purpura	To request a Section 100 (Highly Specialised Drugs Program – Public and Private Hospitals) Authority Required listing for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura.

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Change to listing (Minor Submission)	CARBOHYDRATE, FAT, VITAMINS, MINERALS AND TRACE ELEMENTS Oral powder 400 g Energivit® Nutricia Australia Pty Ltd	Proven inborn errors of protein metabolism	To request a formulation change of Energivit for the dietary management of proven inborn errors of protein metabolism.
Change to listing (Minor Submission)	CARFILZOMIB Powder for injection 10 mg Powder for injection 30 mg Powder for injection 60 mg Kyprolis® Amgen Australia Pty Ltd	Multiple myeloma	To request: <ul style="list-style-type: none"> • A change to authority level from telephone authority to streamlined authority for both initial and continuing treatment • An amendment to the current dosing regimen of carfilzomib to allow a weekly dosing regimen of 70 mg/m² carfilzomib and dexamethasone • An increase in the maximum amount from 120 mg to 160 mg to allow for the weekly dosing of 70 mg/m² carfilzomib and dexamethasone
New listing (Minor Submission)	CATIONIC OPHTHALMIC EMULSION, PRESERVATIVE FREE Eye drops containing light mineral oil 0.5% and mineral oil 0.5%, 10 mL Cationorm® Seqiris (Australia) Pty Ltd	Severe dry eye syndrome	To request an Authority Required (STREAMLINED) PBS listing for the treatment of severe dry eye syndrome.

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Change to listing (Major Submission)	CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX Lyophilised powder for I.M. injection 300 units Lyophilised powder for I.M. injection 500 units Dysport® Ipsen Pty Ltd	Focal spasticity of the upper limb	To request an extension to the current Section 100 (Botulinum Toxin Program) Authority Required (STREAMLINED) listing to include the treatment of focal spasticity of the upper limb in patients with cerebral palsy aged 2 years or older.
New listing (Minor Submission)	DARATUMUMAB 100 mg/5 mL injection, 5 mL vial 400 mg/20 mL injection, 20 mL vial Darzalex® Janssen-Cilag Pty Ltd	Multiple myeloma	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of second-line multiple myeloma in combination with bortezomib and dexamethasone.
New listing (Major Submission)	DAROLUTAMIDE Tablet 300 mg Nubeqa® Bayer Australia Pty Ltd	Prostate cancer	To request an Authority Required listing for the treatment of non-metastatic castration-resistant prostate cancer.

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Change to listing (Major Submission)	DOLUTEGRAVIR + LAMIVUDINE Tablet containing dolutegravir 50 mg (as sodium) with lamivudine 300 mg Dovato® ViiV Healthcare Australia Pty Ltd	Human immunodeficiency virus (HIV) infection	To request an extension of the current Section 100 (Highly Specialised Drugs Program - Community Access) Authority Required (STREAMLINED) listing to include the treatment of HIV infection in antiretroviral therapy experienced patients.
Change to listing (Minor Submission)	DULAGLUTIDE Injection 1.5 mg in 0.5 mL single dose pre-filled pen Trulicity® Eli Lilly Australia Pty Ltd	Type 2 Diabetes Mellitus (T2DM)	To request an Authority Required (STREAMLINED) listing for use in combination with insulin and metformin for the treatment of patients with T2DM.

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New listing (Minor Submission)	<p>ENOXAPARIN</p> <p>Injection containing enoxaparin sodium 100 mg (10,000 I.U. anti-Xa) in 1 mL pre-filled syringe Injection containing enoxaparin sodium 120 mg (12,000 I.U. anti-Xa) in 0.8 mL syringe Injection containing enoxaparin 150 mg (15,000 I.U. anti-Xa) in 1.0 mL syringe; Injection containing enoxaparin sodium 20 mg (2,000 I.U. anti-Xa) in 0.2 mL pre-filled syringe Injection containing enoxaparin sodium 40 mg (4,000 I.U. anti-Xa) in 0.4 mL pre-filled syringe Injection containing enoxaparin sodium 60 mg (6,000 I.U. anti-Xa) in 0.6 mL pre-filled syringe Injection containing enoxaparin sodium 80 mg (8,000 I.U. anti-Xa) in 0.8 mL syringe.</p> <p>Enoxapo®</p> <p>Apotex Pty Ltd</p>	Prevention and treatment of deep vein thrombosis; haemodialysis	To request the Restricted Benefit listing of a biosimilar enoxaparin for the same indications as the originator brand Clethane Safety-Lock.

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New listing (Minor Submission)	EPINEPHRINE I.M Injection, 150 micrograms in 0.3 mL, pen device I.M Injection, 300 micrograms in 0.3 mL, pen device Symjepi® Emerge Health Pty Ltd	Acute allergic reactions including anaphylaxis	To request the Authority Required PBS listing of epinephrine for the emergency treatment of allergic reactions.
New listing (Minor Submission)	FOSNETUPITANT (AS CHLORIDE HYDROCHLORIDE)/PALONOSETRON (AS HYDROCHLORIDE) Powder for Injection containing fosnetupitant 235 mg and palonosetron 250 mg AKYNZEO IV® Mundipharma Pty Limited	Nausea and vomiting	To request the General Schedule and Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) PBS listing of an IV form of fosnetupitant/palonosetron under the same conditions as the capsule form.
New listing (Major Submission)	FULVESTRANT Injection 250 mg in 5 mL pre-filled syringe Faslodex® AstraZeneca Pty Ltd	Breast cancer	To request an Authority Required (STREAMLINED) listing for the treatment of patients with hormone receptor positive (HR+), human epidermal growth factor receptor-2 negative (HER2-) advanced breast cancer.

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New listing (Minor Submission)	<p>GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS</p> <p>Sachets containing oral powder 31 g, 30</p> <p>Tylactin Build 20®</p> <p>Cortex Health Pty Ltd</p>	Tyrosinaemia	To request the Restricted Benefit listing of Tylactin Build 20 for the management of tyrosinaemia.
New listing (Minor Submission)	<p>GUSELKUMAB</p> <p>Solution for injection 10 mg in 1 mL pen device</p> <p>Tremfya®</p> <p>Janssen-Cilag Pty Ltd</p>	Severe chronic plaque psoriasis	To request the Authority Required (Written) PBS listing of a pre-filled pen presentation of guselkumab (TREMFYA®) 100 mg under the same conditions as the existing pre-filled syringe presentation.

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New listing (Major Submission)	<p>INDACATEROL + GLYCOPYRRONIUM + MOMETASONE</p> <p>Capsule containing powder for oral inhalation mometasone furoate 80 micrograms with indacaterol 150 micrograms (as acetate) with glycopyrronium 50 micrograms (as bromide) (for use in Breezhaler)</p> <p>Capsule containing powder for oral inhalation mometasone furoate 160 micrograms with indacaterol 150 micrograms (as acetate) with glycopyrronium 50 micrograms (as bromide) (for use in Breezhaler)</p> <p>Enerzair Breezhaler®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p>	Asthma	To request an Authority Required (STREAMLINED) listing for the treatment of patients with severe asthma who are inadequately controlled on a long acting beta agonist in combination with inhaled corticosteroid (LABA/ICS).

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<p>New listing (Major Submission)</p>	<p>INDACATEROL+ MOMETASONE</p> <p>Capsule containing powder for oral inhalation mometasone furoate 80 micrograms with indacaterol 150 micrograms (as acetate) (for use in Breezhaler)</p> <p>Capsule containing powder for oral inhalation mometasone furoate 160 micrograms with indacaterol 150 micrograms (as acetate) (for use in Breezhaler)</p> <p>Capsule containing powder for oral inhalation mometasone furoate 320 micrograms with indacaterol 150 micrograms (as acetate) (for use in Breezhaler)</p> <p>Aectura Breezhaler®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p>	<p>Asthma</p>	<p>To request an Authority Required (STREAMLINED) listing for the treatment of asthma.</p>
<p>Change to listing (Major Submission)</p>	<p>IXEKIZUMAB</p> <p>Injection 80 mg in 1 mL single dose pre-filled pen</p> <p>Taltz®</p> <p>Eli Lilly Australia Pty Ltd</p>	<p>Ankylosing spondylitis</p>	<p>To request an extension to the current Authority Required listing to include the treatment of patients with active ankylosing spondylitis.</p>

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New listing (Major Submission)	LANADELUMAB Solution for subcutaneous injection 300 mg in 2 mL 300 mg in 2 mL pre-filled syringe Takhzyro® Shire Australia Pty Ltd	Hereditary angioedema	Resubmission to request an Authority Required listing for the prevention of recurrent attacks of hereditary angioedema (C1-esterase-inhibitor deficiency or dysfunction) in patients aged 12 years and older.
Change to listing (Minor Submission)	MILK POWDER SYNTHETIC LOW CALCIUM Oral powder 400 g Locasol® Nutricia Australia Pty Ltd	Hypercalcaemia	To request a formulation change of Locasol for the dietary management of hypercalcaemia.
New listing (Major Submission)	MOGAMULIZUMAB Solution concentrate for I.V. infusion 20 mg in 5 mL Poteligeo® Kyowa Kirin Australia Pty Ltd	Cutaneous T-Cell Lymphoma (CTCL)	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (Written) listing for patients with relapsed or refractory CTCL who have been previously treated with at least one prior systemic therapy.

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New listing (Major Submission)	<p>NIVOLUMAB + IPILIMUMAB</p> <p>Nivolumab: Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL</p> <p>Opdivo®</p> <p>Ipilimumab: Injection concentrate for I.V. infusion 50 mg in 10 mL</p> <p>Yervoy®</p> <p>Bristol-Myers Squibb Australia Pty Ltd</p>	Non-small cell lung cancer (NSCLC)	To request an extension to the current Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listings for nivolumab and ipilimumab to include the first-line treatment of patients with stage IV NSCLC.
Change to listing (Major Submission)	<p>NUSINERSEN</p> <p>Solution for injection 12 mg in 5 mL</p> <p>Spinraza®</p> <p>Biogen Australia Pty Ltd</p>	Spinal muscular atrophy (SMA)	Resubmission to request a Section 100 (Highly Specialised Drugs Program – Public and Private Hospitals) Authority Required listing for the treatment of patients with pre-symptomatic, infantile and childhood-onset SMA.
New listing (Major Submission)	<p>OCRELIZUMAB</p> <p>Solution concentrate for I.V. infusion 300 mg in 10 mL</p> <p>Ocrevus®</p> <p>Roche Products Pty Ltd</p>	Primary progressive multiple sclerosis (PPMS)	Resubmission to request a Section 100 (Highly Specialised Drugs Program – Public and Private Hospitals) Authority Required listing for the treatment of adult patients with PPMS in certain circumstances.

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Change to listing (Major Submission)	OLAPARIB Tablet 100 mg Tablet 150 mg Lynparza® AstraZeneca Pty Ltd	Ovarian, fallopian tube or primary peritoneal cancer	Resubmission to request a Authority Required listing for newly diagnosed advanced BRCA-mutated high grade epithelial ovarian, fallopian tube or primary peritoneal cancer in response (complete or partial) to first-line platinum-based chemotherapy.
Change to listing (Major Submission)	OSIMERTINIB Tablet 40 mg Tablet 80 mg Tagrisso® AstraZeneca Pty Ltd	Non-small cell lung cancer (NSCLC)	Resubmission to request an Authority Required listing for the first line treatment of patients with Stage IIIB (locally advanced) or Stage IV (metastatic), epidermal growth factor receptor mutation positive NSCLC.
New listing (Minor Submission)	PROTEIN FORMULA WITH VITAMINS AND MINERALS, LOW IN POTASSIUM, PHOSPHORUS, CALCIUM, CHLORIDE AND VITAMIN A Oral liquid 125mL, 24 Renastep® Vitaflo Australia Pty Ltd	Dietary management of children with chronic renal failure from 3-18 years of age	Resubmission to request the Authority Required (STREAMLINED) listing of Renastep for the dietary management of children aged 3-18 years with chronic renal failure (CRF).

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Change to listing (Minor Submission)	QUADRIVALENT INFLUENZA VACCINE, SPLIT VIRION, INACTIVATED Injection 0.5 mL Fluarix Tetra® GlaxoSmithKline Australia Pty Ltd	Prevention of seasonal influenza	To request that Fluarix Tetra be included on the NIP for infants and young children aged 6 months to 5 years of age eligible for free vaccination under the NIP for the prevention of seasonal influenza.
New listing (Major Submission)	RAVULIZUMAB Solution concentrate for I.V. infusion 300 mg in 30 mL Ultomiris® Alexion Pharmaceuticals Australasia Pty Ltd	Paroxysmal nocturnal haemoglobinuria (PNH)	To request a Section 100 (Highly Specialised Drugs Program – Public and Private Hospitals) Authority Required listing for the treatment of adult patients with PNH.
New listing (Major Submission)	RIBOCICLIB Tablet 200 mg Kisqali® Novartis Pharmaceuticals Australia Pty Ltd	Breast cancer	To request an Authority Required listing for the treatment of postmenopausal women with hormone receptor positive (HR+), human epidermal growth factor receptor 2 negative (HER2-) advanced or metastatic breast cancer in combination with fulvestrant.

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Change to listing (Minor Submission)	RIFAMPICIN Capsule 150 mg Capsule 300 mg Rimycin 150® Rimycin 300® Mylan	For the treatment of mycobacterium ulcerans infections (Buruli ulcer)	Request to extend the indication for rifampicin to include the treatment of mycobacterium ulcerans infections (Buruli ulcer).
New listing (Minor Submission)	RIVAROXABAN Tablet 2.5 mg Xarelto® Bayer Australia	Coronary Artery Disease (CAD) and Peripheral Artery Disease (PAD)	Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients at high risk of recurrent cardiovascular events with CAD or PAD who meet certain conditions.
New listing (Major Submission)	SELEXIPAG Tablet 200 microgram Tablet 400 microgram Tablet 600 microgram Tablet 800 microgram Tablet 1 mg Tablet 1.2 mg Tablet 1.4 mg Tablet 1.6 mg Uptravi® Janssen-Cilag Pty Ltd	Pulmonary arterial hypertension (PAH)	To request a Section 100 (Highly Specialised Drugs Program – Public and Private Hospitals) Authority Required listing for PAH as a sequential add-on therapy to an endothelin receptor antagonist (ERA) and a phosphodiesterase type 5 (PDE-5) inhibitor.

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New listing (Major Submission)	SIPONIMOD Tablet 250 micrograms Tablet 2 mg Mayzent® Novartis Pharmaceuticals Australia Pty Ltd	Multiple sclerosis (MS)	Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with a history of relapsing forms of MS who meet certain conditions.
New listing (Major Submission)	TAFAMIDIS Capsule 61 mg Vyndamax® Pfizer Australia Pty Ltd	Transthyretin amyloid cardiomyopathy (ATTR-CM)	To request an Authority Required listing for the treatment of ATTR-CM.
New listing (Minor Submission)	TERBUTALINE Powder for oral inhalation in breath actuated device containing terbutaline sulfate 500 micrograms per dose, 120 doses Bricanyl® Turbuhaler® AstraZeneca Pty Ltd	Bronchospasm	To request the Authority Required (STREAMLINED) listing of a new terbutaline inhaler device under the same conditions as the current inhaler presentation.

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Change to listing (Minor Submission)	TIOTROPIUM Solution for oral inhalation 2.5 micrograms (as bromide monohydrate) per actuation (60 actuations) Spiriva Respimat® Boehringer Ingelheim Pty Ltd	Bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease (COPD); severe asthma	To request a change to the PBS listing to amend the device to a reusable inhaler device with a refill cartridge containing tiotropium.
Change to listing (Minor Submission)	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 Spiolto Respimat® Boehringer Ingelheim Pty Ltd	Chronic obstructive pulmonary disease (COPD)	To request a change to the PBS listing to amend the device to a reusable inhaler device with a refill cartridge containing tiotropium and olodaterol.
New listing (Minor Submission)	TOPOTECAN Solution concentrate for I.V. infusion 4 mg in 4 mL (as hydrochloride) Topotecan Accord® Accord Healthcare	Advanced metastatic ovarian cancer	To request a Section 100 (Efficient Funding of Chemotherapy Program), Authority Required (STREAMLINED) listing of a generic brand of topotecan under the same conditions as the existing brand Hycamtin®.

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Change to listing (Minor Submission)	TRIGLYCERIDES MEDIUM CHAIN FORMULA Oral powder 400 g Monogen® Nutricia Australia Pty Ltd	Dietary management of conditions requiring a source of medium chain triglycerides, hyperlipoproteinaemia type 1, long chain fatty acid oxidation disorders, chlyous ascites and chylothorax	To request a formulation change of Monogen for all indications for which it is currently PBS listed.
Change to listing (Minor Submission)	VENETOCLAX Pack containing 14 tablets venetoclax 10 mg and 7 tablets venetoclax 50 mg and 7 tablets venetoclax 100 mg and 14 tablets venetoclax 100 mg Tablet 10 mg Tablet 50 mg Tablet 100 mg Venclexta® AbbVie Pty Ltd	Chronic lymphocytic leukaemia (CLL)	Resubmission to request an Authority Required (telephone/electronic) listing, in combination with obinutuzumab, for the first-line treatment of patients with CLL who have coexisting conditions and are unsuitable for fludarabine based chemotherapy.
Change to listing (Minor Submission)	VITAMINS, MINERALS AND TRACE ELEMENTS WITH CARBOHYDRATE Oral powder 200 g Paediatric Seravit® Nutricia Australia Pty Ltd	Dietary management of conditions requiring a highly restrictive therapeutic diet	To request a formulation change of Paediatric Seravit for the dietary management of conditions requiring a highly restrictive therapeutic diet.

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Change to listing (Minor Submission)	WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE Oral powder 400 g Kindergen® Nutricia Australia Pty Ltd	Chronic Renal Failure (CRF)	To request a formulation change of Kindergen for the dietary management of Chronic Renal Failure (CRF).
Subcommittee report (DUSC Analysis)	Nivolumab Opdivo® Bristol-Myers Squibb Australia Pty Ltd	Non small-cell lung cancer (NSCLC)	To compare the predicted and actual utilisation of Nivolumab for the second line treatment of non-small cell lung cancer in the first 24 months of Pharmaceutical Benefits Scheme (PBS) listing.
Subcommittee report (DUSC Analysis)	Nivolumab Opdivo® Bristol-Myers Squibb Australia Pty Ltd	Renal cell carcinoma (RCC)	To compare the predicted and actual utilisation of Nivolumab for the second line treatment of renal cell carcinoma in the first 24 months of Pharmaceutical Benefits Scheme (PBS) listing.

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Subcommittee report (DUSC Analysis)	Omalizumab Xolair ® Novartis Pharmaceuticals Australia Pty Limited	Chronic spontaneous urticaria	To compare the predicted and actual utilisation of omalizumab for severe chronic spontaneous urticaria since it was PBS listed for this indication.
Matters relating to the Post-market Review of the use of biologics in the treatment of severe chronic plaque psoriasis (CPP): Cost-effectiveness Review	Etanercept; Infliximab Adalimumab; Ustekinumab; Secukinumab; Ixekizumab; Guselkumab; and Tildrakizumab; Risankizumab. (all listed brands)	Chronic Plaque Psoriasis (CPP)	To consider the findings from cost-effectiveness review of biologics for CPP recommended by PBAC in April 2018 following consideration of the Post-market Review. http://www.pbs.gov.au/info/reviews/post-market-biologics This review assesses the cost-effectiveness of biologics in the eligible population under the current Authority Required PBS restrictions for severe CPP and the proposed population presenting with moderate to severe CPP.