

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA  
NOVEMBER 2019 PBAC MEETING**

**Closing date for consumer comments is 9 October 2019**

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  (Minor Submission)	ADALIMUMAB  Injection 80 mg in 0.8 mL pre-filled pen Injection 80 mg in 0.8 mL pre-filled syringe  Humira®  AbbVie Pty Ltd	Moderate to severe hidradenitis suppurativa	To request an Authority Required listing of a new form of adalimumab for the treatment of patients with hidradenitis suppurativa under the same conditions as current listings.
New listing  (Minor Submission)	AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE  Tablets 0.92g, 462  PKU Easy® Tablet  Orpharma Pty Ltd	Phenylketonuria (PKU)	To request a Restricted Benefit listing for the dietary management of patients with PKU.
New listing  (Minor Submission)	AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE AND TYROSINE  Tablets 0.91g, 462  TYR Easy® Tablet  Orpharma Pty Ltd	Tyrosinaemia	To request a Restricted Benefit listing for the dietary management of patients with tyrosinaemia.

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New listing  (Minor Submission)	AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, WITHOUT METHIONINE  Tablets 0.91g, 462  HCU Easy® Tablet  Orpharma Pty Ltd	Pyridoxine non-responsive homocystinuria	To request a Restricted Benefit listing for the dietary management of patients with pyridoxine non-responsive homocystinuria.
New listing  (Minor Submission)	AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, WITHOUT VALINE, LEUCINE AND ISOLEUCINE  Tablets 0.91g, 462  MSUD Easy® Tablet  Orpharma Pty Ltd	Maple syrup urine disease	To request a Restricted Benefit listing for the dietary management of patients with maple syrup urine disease.

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New Listing  (Minor Submission)	AMINO ACID FORMULA WITH VITAMINS WITH MINERALS, WITHOUT VALINE, LEUCINE AND ISOLEUCINE WITH DOCOSHEXAENOIC ACID AND ARACHIDONIC ACID (MSUD EXPLORE)  Sachet containing oral powder 12.5 g, 30  MSUD explore® 5  Vitaflo Australia Pty Limited	Maple syrup urine disease	To request a Restricted Benefit listing for the dietary management of patients with maple syrup urine disease.
Change to listing  (Minor Submission)	ATEZOLIZUMAB  Solution concentrate for I.V. infusion 1200 mg in 20 mL  Tecentriq®  Roche Products Pty Ltd	Small cell lung cancer (SCLC)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first-line treatment of patients with extensive stage SCLC.
Change to listing  (Minor Submission)	ATEZOLIZUMAB  Solution concentrate for I.V. infusion 840 mg in 14 mL  Tecentriq®  Roche Products Pty Ltd	Non-small cell lung cancer (NSCLC)	To request the addition of a new vial size and to amend the current dosing regimen of atezolizumab for second-line NSCLC and the recommended listing for first-line NSCLC to allow clinician choice of either: <ul style="list-style-type: none"> <li>• 1,200 mg Q3W dosing, or</li> <li>• 1,680 mg Q4W dosing.</li> </ul>

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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)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of patients with highly active auto-antibody positive SLE.
Change to listing  (Minor Submission)	BOTULINUM TOXIN TYPE A PURIFIED NEUROTOXIN COMPLEX  Lyophilised powder for injection 100 units  Botox®  Allergan Australia Pty Limited	Spasticity of the upper limb	To request an extension to the current Section 100 (Botulinum Toxin Program) Authority Required (STREAMLINED) listing for moderate to severe spasticity of the upper limb following a stroke to include the treatment of patients with moderate to severe spasticity of the upper limb following an acute event, consistent with the March 2019 PBAC recommendation for clostridium botulinum type A (Dysport®).
New listing  (Major Submission)	BRIGATINIB  Tablet 30 mg Tablet 90 mg Tablet 180 mg Pack containing 7 tablets containing brigatinib 90 mg and 21 tablets containing brigatinib 180 mg  Alunbrig®  Takeda Pharmaceuticals Australia Pty Ltd	Non-small cell lung cancer (NSCLC)	To request an Authority Required listing for the treatment of patients with locally advanced or metastatic anaplastic lymphoma kinase positive NSCLC.

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Change to listing  (Major Submission)	BRIVARACETAM  Tablet 25 mg Tablet 50 mg Tablet 75 mg Tablet 100 mg Oral solution 10mg per mL, 300 mL  Briviact®  UCB Australia Proprietary Limited	Epilepsy	To request a change to the current Authority Required (STREAMLINED) listings for the treatment of patients with intractable partial epileptic seizures, to allow use in patients aged less than 16 years.
New listing  (Major Submission)	BROLUCIZUMAB  Solution for intravitreal injection 19.8 mg in 0.165 mL pre-filled syringe  Beovu®  Novartis Pharmaceuticals Australia Pty Limited	Subfoveal choroidal neovascularisation (CNV)	To request an Authority Required listing for the treatment of patients with CNV due to age-related macular degeneration.

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New listing  (Minor Submission)	<b>BUDESONIDE WITH FORMOTEROL</b>  Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses  Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses  Symbicort® Turbuhaler® 200/6; Symbicort® Rapihaler® 100/3  AstraZeneca Pty Ltd	Asthma	Resubmission to request an Authority Required (STREAMLINED) listing for the first-line treatment of patients with mild asthma.
New listing  (Minor submission)	<b>BUPRENORPHINE</b>  100 mg/0.5 mL modified release injection, 0.5 mL syringe 300 mg/1.5 mL modified release injection, 1.5 mL syringe  Sublocade®  Indivior Pty Ltd	Opiate dependence	Consider the deferred request for a Section 100 (Opiate Dependence Treatment Program) listing for the treatment of patients with opioid use disorder.

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<p>New listing  (Major Submission)</p>	<p><b>BUPRENORPHINE WITH NALOXONE</b></p> <p>Tablet (sublingual) containing 0.7 mg buprenorphine hydrochloride with 0.18 mg naloxone hydrochloride                      Tablet (sublingual) containing 1.4 mg buprenorphine hydrochloride and 0.36 mg naloxone hydrochloride                      Tablet (sublingual) containing 2.9 mg buprenorphine hydrochloride and 0.71 mg naloxone hydrochloride                      Tablet (sublingual) containing 5.7 mg buprenorphine hydrochloride and 1.4 mg naloxone hydrochloride                      Tablet (sublingual) containing 8.6 mg and 2.1 mg naloxone hydrochloride                      Tablet (sublingual) containing 11.4 mg buprenorphine hydrochloride and 2.9 mg naloxone hydrochloride</p> <p>Zubsolv®</p> <p>Mundipharma Pty Limited</p>	<p>Opiate dependence</p>	<p>To request a Section 100 (Opiate Dependence Treatment Program) Restricted Benefit listing for the treatment of patients with opiate dependence.</p>

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Change to listing  (Major Submission)	CERTOLIZUMAB PEGOL  Injection 200 mg in 1 mL single use pre-filled syringe Solution for injection 200 mg in 1 mL pre-filled pen  Cimzia®  UCB Australia Proprietary Limited	Non-radiographic axial spondyloarthritis (nr-axSpA)	To request an Authority Required listing for the treatment of patients with nr-axSpA who meet certain conditions.
Change to recommended listing  (Minor Submission)	CERTOLIZUMAB PEGOL  Injection 200 mg in 1 mL single use pre-filled syringe Solution for injection 200 mg in 1 mL pre-filled pen  Cimzia®  UCB Australia Proprietary Limited	Chronic plaque psoriasis (CPP)	Resubmission to request reconsideration of the basis of the PBAC's March 2019 recommendation for the Authority Required listing for the treatment of patients with CPP.
New listing  (Major Submission)	DARATUMUMAB  Solution concentrate for I.V infusion 100 mg in 5 mL Solution concentrate for I.V infusion 400 mg in 20 mL  Darzalex®  Janssen-Cilag Pty Ltd	Multiple myeloma	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing, in combination with bortezomib and dexamethasone, for the treatment of patients with relapsed or refractory multiple myeloma who have progressive disease after one prior line of therapy.

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New listing  (Major Submission)	DARUNAVIR with COBICISTAT with EMTRICITABINE and TENOFOVIR ALAFENAMIDE  Tablet containing darunavir 800 mg with cobicistat 150 mg with emtricitabine 200 mg and tenofovir alafenamide 10 mg  Symtuza®  Janssen-Cilag Pty Ltd	Human immunodeficiency virus (HIV) infection	To request a Section 100 (Highly Specialised Drugs Program - Community Access) Authority Required (STREAMLINED) listing for the treatment of patients with HIV infection.
Change to listing  (Minor Submission)	DIMETHYL FUMARATE  Capsule (modified release) 120 mg Capsule (modified release) 240 mg  Tecfidera®  Biogen Australia Pty Ltd	Relapsing-remitting multiple sclerosis (RRMS)	To request the current Authority Required listings of dimethyl fumarate for the treatment of patients with RRMS be changed to Authority Required (STREAMLINED).
Change to listing  (Major 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)	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®  AstraZeneca Pty Ltd	Non-small cell lung cancer (NSCLC)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of patients with unresectable Stage III NSCLC whose disease has not progressed following platinum-based chemoradiation therapy.
New listing  (Major Submission)  <i>Withdrawn</i>	ERENUMAB  Injection 70 mg in 1 mL single dose pre-filled pen Injection 140 mg in 1 mL single dose pre-filled pen  Aimovig®  Novartis Pharmaceuticals Australia Pty Limited	Chronic migraine	Resubmission to request an Authority Required (STREAMLINED) listing for the prophylactic treatment of adult patients with chronic migraine who have experienced inadequate response, intolerance or a contraindication to at least three prior preventive migraine medications.

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Change to listing  (Minor Submission)	EVOLOCUMAB  Injection 420 mg in 3.5 mL single use pre-filled cartridge  Injection 140 mg in 1 mL single use pre-filled pen  Repatha®  Amgen Australia Pty Ltd	Hypercholesterolaemia	Resubmission to request an Authority Required listing for the treatment of patients with hypercholesterolaemia who are very high risk for atherosclerotic cardiovascular disease (ASCVD) or inadequately controlled on optimal doses of high potency statins and ezetimibe.
New listing  (Major Submission)	FREMANEZUMAB  Injection 225 mg in 1.5 mL pre-filled syringe  Ajovy®  Teva Pharma Australia Pty Limited	Chronic migraine	To request an Authority Required (STREAMLINED) listing for the prophylactic treatment of adult patients with chronic migraine who have experienced inadequate response, intolerance or a contraindication to at least three prior preventive migraine medications.

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New listing  (Minor Submission)	GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS  Sachets containing oral powder 16 g, 60 Sachets containing oral powder 32 g, 30  PKU Build® 10 PKU Build® 20  Cortex Health Pty Ltd	Phenylketonuria	To request changes to the formulation of PKU Build 10 and PKU Build 20.
Change to listing  (Major Submission)	HIGH DOSE INACTIVATED TRIVALENT INFLUENZA VACCINE (SPLIT VIRION)  Injection 0.5 mL  Fluzone® High-Dose  Sanofi-Aventis Australia Pty Ltd	Prevention of seasonal influenza	Resubmission to request that the PBAC review the basis of its March 2018 recommendation for National Immunisation Program (NIP) listing for the prevention of seasonal influenza in patients aged 65 years and over.
Change to listing  (Major Submission)	IBRUTINIB  Capsule 140 mg  Imbruvica®  Janssen-Cilag Pty Ltd	Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)	Resubmission to request an Authority Required listing for the treatment of patients with previously untreated CLL or SLL with evidence of one or more 17p chromosomal deletions.

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Change to listing (Major Submission)	INACTIVATED QUADRIVALENT INFLUENZA VACCINE (SPLIT VIRION)  Injection 0.5 mL  FluQuadri®  Sanofi-Aventis Australia Pty Ltd	Prevention of seasonal influenza	To request an extension to the current National Immunisation Program (NIP) listing to include all people aged 6 months and older currently eligible for seasonal influenza vaccination under the NIP for the prevention of seasonal influenza.
Change to listing (Minor Submission)	INCOBOTULINUMTOXIN A  Lyophilised powder for injection 100 units  Xeomin®  Merz Australia Pty Ltd	Spasticity of the upper limb	To request an extension to the current Section 100 (Botulinum Toxin Program) Authority Required (STREAMLINED) listing for moderate to severe spasticity of the upper limb following a stroke to include the treatment of patients with moderate to severe spasticity of the upper limb following an acute event, consistent with the March 2019 PBAC recommendation for clostridium botulinum type A (Dysport®).
New listing (Minor Submission)	ISOTRETINOIN  Capsule 30 mg  Oratane®  Oraderm Pharmaceuticals Pty Ltd	Severe cystic acne	To request an Authority Required (STREAMLINED) listing of a new form of isotretinoin for the treatment of patients with severe cystic acne.

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Change to listing  (Minor Submission)	LEVODOPA with CARBIDOPA  Intestinal gel containing levodopa 20 mg with carbidopa monohydrate 5 mg per mL, 100 mL  Duodopa®  AbbVie Pty Ltd	Parkinson disease	To request: <ul style="list-style-type: none"> <li>• General Schedule and Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listings with a new maximum quantity of 4 packs, with the same listing conditions as the current listings.</li> <li>• An additional clinical criterion for the current listings: 'patient must require continuous administration without an overnight break or a total dose per day of levodopa &gt; 2000 mg'</li> </ul>
New listing  (Major Submission)	LORLATINIB  Tablet 25 mg Tablet 100 mg  Lorviqua®  Pfizer Australia Pty Ltd	Non-small cell lung cancer (NSCLC)	To request an Authority Required listing for the treatment of patients with metastatic anaplastic lymphoma kinase (ALK) positive NSCLC previously treated with one or more ALK tyrosine kinase inhibitors.
New listing  (Major Submission)	MULTICOMPONENT MENINGOCOCCAL GROUP B VACCINE  Injection 0.5 mL  Bexsero®  GlaxoSmithKline Australia Pty Ltd	Prevention of meningococcal B disease	Resubmission to request listing on the National Immunisation Program (NIP) for the routine immunisation of infants and adolescents, and catch-up programs for high risk populations for the prevention of IMD caused by <i>N. meningitidis</i> group B strains.

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New listing  (Major Submission)	NERATINIB  Tablet 40 mg  Nerlynx®  Specialised Therapeutics Australia Pty Ltd	Early breast cancer	Resubmission to request an Authority Required listing for extended adjuvant treatment of patients with human epidermal growth factor receptor-2 positive (HER2+) early breast cancer who have received prior adjuvant trastuzumab therapy.
New Listing  (Minor Submission)	NUSINERSEN  Solution for injection 12 mg in 5 mL  Spinraza®  Biogen Australia Pty Ltd	Spinal muscular atrophy	Consider the deferred request for a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of patients with pre-symptomatic, infantile and childhood-onset, spinal muscular atrophy.

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Change to listing  (Major Submission)	NIVOLUMAB  Nivolumab: Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL  Opdivo®  IPILIMUMAB  Ipilimumab: Injection concentrate for I.V. infusion 50 mg in 10 mL Injection concentrate for I.V. infusion 200 mg in 40 mL  Yervoy®  Bristol-Myers Squibb Australia Pty Ltd	Melanoma	Resubmission to request an extension of the current Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listings for nivolumab and ipilimumab for the treatment of unresectable Stage III or IV malignant melanoma to allow use as first-line therapies in patients who are BRAF V600 mutation positive.
Change to listing  (Major Submission)	OLAPARIB  Tablet 100 mg Tablet 150 mg  Lynparza®  AstraZeneca Pty Ltd	Ovarian, fallopian tube or primary peritoneal cancer	To request an Authority Required listing for the maintenance treatment of advanced high grade epithelial ovarian, fallopian tube or primary peritoneal cancer, in class 4 or 5 BRCA1/2 mutation positive patients who are in response to platinum-based chemotherapy.

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<b>Submission type</b> (new listing, change to listing)	<b>Drug Name, form(s), strength(s) and Sponsor</b> (Drug name, form, strength, Trade name®, Sponsor)	<b>Drug Type and Use</b> (What is the drug used to treat?)	<b>Listing requested by Sponsor / Purpose of Submission</b> (Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased.)
New listing  (Major Submission)	PATIROMER  Powder for oral liquid 8.4 g Powder for oral liquid 16.8 g  Veltassa®  Vifor Pharma Pty Limited	Hyperkalaemia	To request an Authority Required listing for the prevention of hyperkalaemia in patients with stage III or greater chronic kidney disease who have experienced a recent episode of hyperkalaemia requiring pharmacological intervention.
New listing  (Minor Submission)	PEGFILGRASTIM  Injection 6 mg in 0.6 mL single use pre-filled syringe  Ziextenzo®  Sandoz Pty Ltd	Chemotherapy-induced neutropenia	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing of a biosimilar pegfilgrastim under the same conditions as the reference biologic.
Change to listing  (Minor Submission)	PEMBROLIZUMAB  Solution concentrate for I.V. infusion 100 mg in 4 mL  Keytruda®  Merck Sharp & Dohme (Australia) Pty Ltd	Melanoma	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the adjuvant treatment of patients who have had completely surgically resected Stage IIIB-D malignant melanoma.

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New listing  (Major Submission)	POLATUZUMAB VEDOTIN  Powder for I.V. infusion 140 mg  Polivy®  Roche Products Pty Ltd	Diffuse large B-cell lymphoma (DLBCL)	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of patients with relapsed or refractory DLBCL who are ineligible for stem cell transplantation.
Change to listing  (Minor Submission)	POMALIDOMIDE  Capsule 3 mg Capsule 4 mg  Pomalyst®  Celgene Pty Ltd	Multiple myeloma	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required listing in combination with bortezomib and dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received at least one prior treatment regimen (including lenalidomide).
Change to listing  (Minor Submission)	PREDNISOLONE ACETATE WITH PHENYLEPHRINE  Eye drops containing prednisolone acetate 10 mg with phenylephrine hydrochloride 1.2 mg per mL, 10 mL  Prednefrin® Forte  National Aboriginal Community Controlled Health Organisation	Severe inflammation of the eye	To request a Restricted Benefit listing for the treatment of severe inflammation of the eye following cataract surgery for patients who identify as Aboriginal and Torres Strait Islander.

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New Listing  (Minor Submission)	PROTEIN FORMULA WITH VITAMINS AND MINERALS, AND LOW IN POTASSIUM, PHOSPHORUS, CALCIUM, CHLORIDE AND VITAMIN A  Oral liquid 125 mL, 24  Renastep®  Vitaflo Australia Pty Limited	Chronic kidney disease (CKD)	To request an Authority Required (STREAMLINED) listing for the dietary management of paediatric CKD in patients aged 3 years and over who require a modified protein diet.
Change to listing  (Major Submission)	RUXOLITINIB  Tablet 5 mg Tablet 10 mg Tablet 15 mg Tablet 20 mg  Jakavi®  Novartis Pharmaceuticals Australia Pty Limited	Polycythemia vera (PV)	To request an Authority Required listing for the treatment of patients with PV who are resistant to or intolerant of hydroxycarbamide (hydroxyurea).

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New Listing  (Minor Submission)	SALBUTAMOL  Pressurised inhalation 100 micrograms (as sulfate) per dose, 200 doses (CFC-free formulation)  Ventolin®  GlaxoSmithKline Australia Pty Ltd	Asthma;  Chronic obstructive pulmonary disease (COPD)	To request an Unrestricted Benefit listing of a new presentation of salbutamol metered dose inhaler with a dose counter.
New listing  (Major Submission)	SEMAGLUTIDE  Injection 2 mg in 1.5 mL pre-filled syringe Injection 4 mg in 3 mL pre-filled syringe  Ozempic®  Novo Nordisk Pharmaceuticals Pty Limited	Type 2 diabetes mellitus (T2DM)	To request an Authority Required (STREAMLINED) listing for use in combination with metformin and/or a sulfonylurea for the treatment of patients with T2DM.
New listing  (Major Submission)	SIPONIMOD  Tablet 250 micrograms Tablet 2 mg  Mayzent®  Novartis Pharmaceuticals Australia Pty Limited	Secondary progressive multiple sclerosis (SPMS)	To request an Authority Required listing for the treatment of patients with SPMS.

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New listing  (Minor Submission)	TACROLIMUS  Capsule 3 mg (once daily prolonged release)  Advagraf XL®  Astellas Pharma Australia Pty Ltd	Management of rejection in patients following organ or tissue transplantation	To request an unrestricted General Schedule listing and a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing of a new form of tacrolimus under the same conditions as the current 500 microgram, 1 mg and 5 mg prolonged-release listings.
New listing  (Major Submission)	TALAZOPARIB  Capsule 250 micrograms (as tosilate) Capsule 1 mg (as tosilate)  Talzenna®  Pfizer Australia Pty Ltd	Advanced breast cancer	To request an Authority Required listing for the treatment of patients with germline BRCA mutated HER2-negative advanced breast cancer who have been previously treated with a taxane and/or an anthracycline.
Change to recommended listing  (Minor Submission)	TEZACAFTOR WITH IVACAFTOR  Tablet containing tezacaftor 100 mg with ivacaftor 150 mg  Symdeko®  Vertex Pharmaceuticals (Australia) Pty Ltd	Cystic Fibrosis (CF)	Resubmission to request an extension to the PBAC's March 2019 recommendation for Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of CF in patients aged 12 years or older who have one copy of the F508del mutation and another residual function (RF) mutation in the CF transmembrane conductance regulator (CFTR) gene to be for patients aged 12 years or older who have at least one copy of the RF mutation in the CFTR gene.

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New listing  (Minor Submission)	TOLVAPTAN  Tablet 15 mg  Tablet 30 mg  Pack containing 28 tablets 15 mg and 28 tablets 45 mg Pack containing 28 tablets 30 mg and 28 tablets 60 mg Pack containing 28 tablets 30 mg and 28 tablets 90 mg  Jinarc®  Otsuka Australia Pharmaceutical Pty Ltd	Autosomal dominant polycystic kidney disease (ADPKD)	To request: <ul style="list-style-type: none"> <li>• listing of two new forms (15 mg and 30 mg tablets) of tolvaptan for the treatment of patients with ADPKD;</li> <li>• to change the current General Schedule listings of tolvaptan to Section 100 (Highly Specialised Drugs Program - Community Access); and</li> <li>• to change the authority level for initial treatment from a written to telephone authority.</li> </ul>
Change to listing  (Major Submission)	TRASTUZUMAB EMTANSINE  Powder for I.V. infusion 100 mg Powder for I.V. infusion 160 mg  Kadcyla®  Roche Products Pty Ltd	Early breast cancer	To request an Authority Required Section 100 (Efficient Funding of Chemotherapy Program) listing for the adjuvant treatment of patients with Human epidermal growth factor receptor-2 positive (HER2+) early breast cancer with residual disease following neoadjuvant treatment with HER2-targeted therapy.

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New listing  (Minor Submission)	TRASTUZUMAB  Powder for I.V. infusion 60 mg Powder for I.V. infusion 150 mg  Trazimera®  Pfizer Australia Pty Ltd	Breast cancer Gastric cancer	To request a Section 100 (Efficient Funding of Chemotherapy Program), Authority Required (STREAMLINED) listing of a biosimilar trastuzumab under the same conditions as the reference biologic.
Change to listing  (Major Submission)	TRIFLURIDINE with TIPIRACIL  Tablet containing 15 mg trifluridine with 6.14 mg tipiracil (as hydrochloride) Tablet containing 20 mg trifluridine with 8.19 mg tipiracil (as hydrochloride)  Lonsurf®  Servier Laboratories (Aust.) Pty Ltd	Gastric cancer	To request an Authority Required (STREAMLINED) listing for the treatment of patients with metastatic gastric cancer who have been previously treated with, or are not considered candidates for, currently available therapies.
New listing  (Major Submission)	UPADACITINIB  Tablet (modified release) 15 mg  Trade name to be determined  AbbVie Pty Ltd	Rheumatoid arthritis (RA)	To request an Authority Required listing for the treatment of patients with severe active RA.
Sub-committee report  (DUSC Analysis)	Lenalidomide  Revlimid®  Celgene Pty Limited	Multiple Myeloma.	To compare the 24 month predicted and actual utilisation of lenalidomide as first line therapy for patients with newly diagnosed multiple myeloma.



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	(Tasigna®, Novartis Pharmaceuticals Australia Pty Limited)  Dasatinib  (Sprycel®, Bristol-Myers Squibb Australia Pty Ltd)  Ponatinib  (Iclusig®, Specialised Therapeutics Australia Pty Ltd)		
Sub-committee report  (DUSC Analysis)	Omalizumab  (Xolair® Novartis Pharmaceuticals Australia Pty Limited)  Mepolizumab  (Nucala®, GlaxoSmithKline Australia Pty Ltd)  Benralizumab  (Fesentra®, AstraZeneca Pty Ltd)	Severe allergic and eosinophilic asthma	Review of biologics for uncontrolled severe allergic and eosinophilic asthma

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Sub-committee report  (DUSC Analysis)	Evolocumab (Repatha®, Amgen Australia Pty Limited)	Familial homozygous hypercholesterolaemia	To compare the predicted and actual utilisation of evolocumab for homozygous familial hypercholesterolaemia since PBS listing on 1 December 2016.