

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

Closing date for consumer comments 13 February 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 Medicare Australia or the DVA (noted as Authority required)
- *Authority required (STREAMLINED) benefits* do not require prior approval from Medicare Australia 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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Submission type (new listing, change to listing)	Drug Name, form(s), strength(s) and Sponsor (Drug name, form, strength, Trade name®, Sponsor)	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.)
New listing (Major Submission)	ABEMACICLIB Tablet 50mg Tablet 100mg Tablet 150mg Verzenio® Eli Lilly Australia Pty Ltd	Advanced breast cancer	To request an Authority Required listing for the treatment of non-premenopausal patients with hormone receptor positive (HR+), human epidermal growth factor receptor-2 negative (HER2-) locally advanced or metastatic breast cancer.
Change to listing (Minor Submission)	ALECTINIB Capsule 150 mg Alecensa® Roche Products Pty Ltd	Non-small cell lung cancer (NSCLC)	To request a change in the authority level of the current listing from Authority Required (Telephone) to Authority Required (STREAMLINED) and an increase in the maximum number of repeats from 1 to 5.
New listing (Major Submission)	ALIROCUMAB Injection 75 mg in 1 mL single dose pre-filled pen Injection 150 mg in 1 mL single dose pre-filled pen Praluent® Sanofi-Aventis Australia Pty Ltd	Hypercholesterolaemia	Resubmission to request an Authority Required listing for the treatment of patients: <ul style="list-style-type: none"> • with familial heterozygous hypercholesterolaemia; or • with hypercholesterolaemia with previous acute coronary syndrome and concomitant diabetes.

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Change to listing (Major Submission)	ATEZOLIZUMAB and BEVACIZUMAB Atezolizumab: Solution concentrate for I.V. infusion 1200 mg in 20 mL Bevacizumab: Solution for I.V. infusion 100 mg in 4 mL Solution for I.V. infusion 400 mg in 16 mL Tecentriq® and Avastin® Roche Products Pty Ltd	Non-small cell lung cancer (NSCLC)	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of metastatic NSCLC in combination with platinum-doublet chemotherapy in: <ul style="list-style-type: none"> • epidermal growth factor receptor (EGFR) wild type/ anaplastic lymphoma kinase (ALK) negative patients; or • EGFR/ALK mutation positive patients who have progressed on or after prior treatment with a tyrosine kinase inhibitor (TKI).
New listing (Minor Submission)	BENZATHINE BENZYL PENICILLIN Injection 517 mg in 1.17 mL single use pre-filled syringe Bicillin L-A® Pfizer Australia Pty Ltd	Treatment of infections	To request an unrestricted benefit listing of a new strength of benzathine benzylpenicillin injection.
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 Avastin® Roche Products Pty Ltd	Glioblastoma multiforme/Grade IV glioma (GBM)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy), Authority Required (STREAMLINED) listing for the treatment of relapsed or refractory GBM.

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Change to listing (Major Submission)	BLINATUMOMAB Powder for I.V. infusion 38.5 micrograms Blincyto® Amgen Australia Pty Ltd	Acute lymphoblastic leukaemia (ALL)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) listing for the treatment of patients with B-cell precursor ALL in patients in haematological complete remission with minimal residual disease following chemotherapy.
Change to listing (Minor Submission)	BOTULINUM TOXIN TYPE A Lyophilised powder for injection 100 units Botox® Allergan Australia Pty Ltd	Focal spasticity of the lower limb	Resubmission to request an extension to the current Section 100 (Botulinum Toxin Program) listing to include the treatment of lower limb focal spasticity in adults following stroke, who meet certain conditions.
New listing (Minor Submission)	BUDESONIDE Capsule (modified release) 3 mg Budenofalk® Orphan Australia Pty Ltd	Crohn disease	To request an Authority Required (STREAMLINED) listing for the treatment of patients with mild to moderate Crohn disease.
New listing (Minor Submission)	BUDESONIDE Capsule (modified release) 3 mg Entocort® Emerge Health Pty Ltd	Mild to moderate Crohn disease	Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with mild to moderate Crohn disease.

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New listing (Major Submission)	BUPRENORPHINE Injection (modified release) 100 mg in 0.5 mL pre-filled syringe Injection (modified release) 300 mg in 1.5 mL pre-filled syringe Sublocade® Indivior Pty Ltd	Opiate dependence	To request a Section 100 (Opiate Dependence Treatment Program) listing for the treatment of patients with opioid use disorder.
New listing (Minor Submission)	BUPRENORPHINE Injection 8 mg in 0.16 mL pre-filled syringe Injection 16 mg in 0.32 mL pre-filled syringe Injection 24 mg in 0.48 mL pre-filled syringe Injection 32 mg in 0.64 mL pre-filled syringe Injection 64 mg in 0.18 mL pre-filled syringe Injection 96 mg in 0.27 mL pre-filled syringe Injection 128 mg in 0.36 mL pre-filled syringe Buvidal® Camurus AB	Opiate dependence	Resubmission to request a Section 100 (Opiate Dependence Treatment Program) listing for the treatment of patients with opiate dependence.

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Change to listing (Major Submission)	CABOZANTINIB Tablet 20 mg Tablet 40 mg Tablet 60 mg Cabometyx® Ipsen Pty Ltd	Renal cell carcinoma (RCC)	To request an extension to the current listing for the treatment of Stage IV clear cell variant RCC to include previously untreated patients.
New listing (Minor Submission)	CALCIUM Tablet, chewable, 500 mg (as carbonate) Cal-500® Petrus Pharmaceuticals Pty Ltd	Hyperphosphataemia	To request an Authority Required (STREAMLINED) listing of a new larger pack size of calcium for the treatment of hyperphosphataemia.
Change to listing (Major Submission)	CERTOLIZUMAB PEGOL Injection 200mg in 1 mL pre-syringe pen Solution for injection 200 mg in 1 mL pre-filled pen Cimzia® UCB Australia Pty Ltd	Severe chronic plaque psoriasis	To request an Authority Required listing for the treatment of patients with severe chronic plaque psoriasis.

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Change to listing (Minor Submission)	CLOSTRIDIUM BOTULINUM TYPE A TOXIN – HAEMAGGLUTININ C COMPLEX Lyophilised powder for I.M. injection 300 units Lyophilised powder for I.M. injection 500 units Dysport® Ipsen Pty Ltd	Spasticity of the upper limb	Resubmission to extend the current Section 100 (Botulinum Toxin Program) listing to include treatment of patients with moderate to severe spasticity of the upper limb following an acute event, and to remove the current restriction on the number of treatment periods in a lifetime.
Change to listing (Major Submission)	DABRAFENIB and TRAMETINIB Dabrafenib: Capsule 50 mg Capsule 75 mg Trametinib: Tablet 500 microgram Tablet 2 mg Tafinlar® and Mekinist® Novartis Pharmaceuticals Australia Pty Ltd	Melanoma	To request an Authority required (STREAMLINED) listing for the adjuvant treatment of patients who have had completely surgically resected BRAF V600 mutation positive Stage III malignant melanoma.

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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 for the treatment of multiple myeloma: <ul style="list-style-type: none"> • in combination with bortezomib and dexamethasone for the treatment of relapsed or refractory multiple myeloma in patients who have progressive disease after at least one prior therapy; or • as monotherapy for highly treatment experienced and refractory patients
Change of listing (Major Submission)	DARBEPOETIN ALFA Injection 200 micrograms in 0.4 mL pre-filled syringe Injection 300 micrograms in 0.6 mL pre-filled syringe Injection 500 micrograms in 1 mL pre-filled syringe Aranesp® Amgen Australia Pty Ltd	Chemotherapy-induced anaemia	Resubmission to request a Section 100 (Highly Specialised Drug) Authority Required listing for chemotherapy-induced anaemia.

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Change to listing (Minor Submission)	DASATINIB Tablet 20mg Tablet 50mg Tablet 70mg Tablet 100mg Sprycel® Bristol-Myers Squibb Australia Pty Ltd	Acute lymphoblastic leukaemia (ALL)	To request an extension to the current Authority Required (in writing) listing for the treatment of Philadelphia chromosome positive (Ph+) ALL to include newly diagnosed patients.
Change to listing (Minor Submission)	ENOXAPARIN 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 Clexane® Sanofi-Aventis Australia Pty Ltd	Venous thromboembolism (VTE) prophylaxis	To request an increase in the maximum number of repeats from 0 to 1 for the unrestricted listing of enoxaparin.
New listing (Major Submission)	ERENUMAB Injection 70 mg in 1 mL single dose pre-filled pen Aimovig® Novartis Pharmaceuticals Australia Pty Ltd	Chronic migraine	Resubmission to request an Authority Required (STREAMLINED) listing for prophylaxis in patients with chronic migraine.

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New listing (Major Submission)	EXENATIDE Injection 2 mg in 0.85 mL single dose autoinjector Bydureon® BCise® AstraZeneca Pty Ltd	Type 2 diabetes mellitus (T2DM)	To request an Authority Required (STREAMLINED) listing for use in combination with metformin or sulfonylurea for the treatment of patients with T2DM.
Change to listing (Major Submission)	FLUTICASONE FUROATE with UMECLIDINIUM and VILANTEROL Powder for oral inhalation in breath actuated device containing fluticasone furoate 100 micrograms with umeclidinium 62.5 micrograms (as bromide) and vilanterol 25 micrograms (as trifenate) per dose, 30 doses Trelegy® Ellipta® GlaxoSmithKline Australia Pty Ltd	Chronic Obstructive Pulmonary Disease (COPD)	To request a change to the current clinical criteria to remove the requirement for patients to have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy.
Change to listing (Minor Submission)	INFLIXIMAB Powder for I.V. infusion 100 mg Inflectra® Pfizer Australia Pty Ltd	Crohn disease Fistulating Crohn disease Ulcerative colitis Ankylosing spondylitis Psoriatic arthritis Chronic plaque psoriasis	To request an increase in the maximum quantity of vials from 4 to 5 in the Authority Required (STREAMLINED), subsequent continuing treatment phase for indications for which a 5 mg/kg dose regimen is required.

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New listing (Major Submission)	INSULIN GLARGINE with LIXISENATIDE Injections (human analogue), cartridges, insulin glargine 100 units per mL with lixisenatide 50 micrograms per mL, 3 mL, 5 Injections (human analogue), cartridges, insulin glargine 100 units per mL with lixisenatide 33 micrograms per mL, 3 mL, 5 Soliqua® Sanofi-Aventis Australia Pty Ltd	Type 2 diabetes mellitus (T2DM)	Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with T2DM who have inadequate glycaemic control with basal insulin.
Change to listing (Major Submission)	IVACAFTOR Sachet containing granules 50 mg Sachet containing granules 75 mg Kalydeco® Vertex Pharmaceuticals (Australia) Pty Ltd	Cystic fibrosis (CF)	To request an extension to the current Section 100 (Highly Specialised Drugs Program) Authority Required listing to include the treatment of CF in patients aged 12–24 months who have at least one <i>G551D</i> or other gating (class III) mutation in the CF transmembrane conductance regulator (CFTR) gene.
Change to listing (Minor Submission)	LANREOTIDE Injection 120 mg (as acetate) in single dose pre-filled syringe Somatuline® Autogel® Ipsen Pty Ltd	Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NETs)	To request a Section 100 (Highly Specialised Drug - Community Access), Authority Required (STREAMLINED) listing for the treatment of GEP-NETs.

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Change to listing (Major Submission)	LENALIDOMIDE Capsule 5 mg Capsule 10 mg Capsule 15 mg Revlimid® Celgene Pty Ltd	Multiple myeloma	Resubmission to request an extension to the Section 100 (Highly Specialised Drug Program) Authority Required listing to include maintenance treatment of patients with newly diagnosed multiple myeloma who have undergone an autologous stem cell transplant.
Change to listing (Minor Submission)	LENALIDOMIDE Capsule 5 mg Capsule 10 mg Capsule 15 mg Capsule 25 mg Revlimid® Celgene Pty Ltd	Multiple myeloma	To request the current Authority Required (written) listings of lenalidomide for multiple myeloma be amended to Authority Required (STREAMLINED).
New listing (Major Submission)	LETERMOVIR Tablet 240 mg Prevymis® Merck Sharp and Dohme (Australia) Pty Ltd	Prophylaxis of cytomegalovirus (CMV) infection or disease	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the prophylaxis of cytomegalovirus (CMV) infection or disease in adult CMV-seropositive [R+] recipients of an allogeneic haematopoietic stem cell transplant (allo-HSCT).

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New listing (Major Submission)	LEVONORGESTREL Intrauterine drug delivery system 19.5 mg Kyleena® Bayer Australia Ltd	Contraception	To request a Restricted Benefit listing for contraception.
Change to listing (Minor Submission)	MORPHINE Capsule containing morphine sulfate pentahydrate 10 mg (modified release) Capsule containing morphine sulfate pentahydrate 20 mg (modified release) Kapanol® Mayne Pharma International Pty Ltd	Chronic breathlessness	To request a Restricted Benefit listing on the Palliative Care schedule for the treatment of chronic breathlessness.
New listing (Minor Submission)	NALOXONE 2.2 mg/actuation nasal spray, 2 x 1 actuation Nyxoid® Mundipharma Pty Ltd	Known or suspected opiate overdose	To request an unrestricted listing for known or suspected opiate overdose.

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New listing (Major Submission)	NERATINIB Tablet 40 mg Nerlynx® Specialised Therapeutics Pty Ltd	Early breast cancer (eBC)	To request an Authority Required listing for extended adjuvant treatment of patients with early-stage Human epidermal growth factor receptor-2 positive (HER2+) overexpressed/amplified breast cancer who have received prior adjuvant trastuzumab based therapy.
Change to listing (Minor Submission)	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	Melanoma Non-small cell lung cancer Renal cell carcinoma Squamous cell carcinoma of the head and neck	A request to amend the current 3mg/kg every two weeks (Q2W) dosing regimen of nivolumab for the treatment of unresectable Stage III or Stage IV malignant melanoma to include recent TGA approved changes to dosing and allow clinician choice of either: 1. Weight-based 3mg/kg Q2W dosing, or 2. Fixed 240mg Q2W dosing, or 3. Fixed 480mg Q4W dosing.
Change to listing (Major Submission)	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	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 III or Stage IV malignant melanoma.

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New listing (Minor Submission)	OCRIPLASMIN Solution for intravitreal injection 0.375 mg in 0.3 mL Jetrea® RTU iCare Pharma Distributors	Vitreomacular traction syndrome (VTS)	To request an Authority Required listing of a new form of ocriplasmin for VTS.
New listing (Major Submission) <i>Withdrawn</i>	OLARATUMAB Solution concentrate for I.V. infusion 190 mg in 19 mL Solution concentrate for I.V. infusion 500 mg in 50 mL Lartruvo® Eli Lilly Australia Pty Ltd	Soft tissue sarcoma	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing, in combination with doxorubicin, for the treatment of patients with locally advanced or metastatic soft tissue sarcoma not amenable to curative treatment with radiotherapy or surgery.
New listing (Minor Submission)	PACLITAXEL, NANOPARTICLE ALBUMIN-BOUND Powder for I.V. injection containing 250 mg paclitaxel Abraxane® Specialised Therapeutics Pty Ltd	Adenocarcinoma of the pancreas Breast cancer	To request an Authority Required (STREAMLINED) listing of a new vial size.

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Change to listing (Minor Submission)	PEGVISOMANT Injection set containing powder for injection 10 mg, 30 and diluent, 30 Injection set containing powder for injection 15 mg, 30 and diluent, 30 Injection set containing powder for injection 20 mg, 30 and diluent, 30 Injection set containing powder for injection 20 mg, 1 and diluent, 1 Somavert® Pfizer Australia Pty Ltd	Acromegaly	To request a change to the definition of failure to achieve biochemical control in the current PBS restriction.
Change to listing (Major Submission)	PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® Merck Sharp and Dohme (Australia) Pty Ltd	Metastatic colorectal carcinoma (CRC)	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of locally advanced or metastatic CRC in patients with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumours, who have progressed following prior treatment.
Change to listing (Major Submission)	PERTUZUMAB Solution for I.V. infusion 420 mg in 14 mL Perjeta® Roche Products Pty Ltd	Early breast cancer (eBC)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing in combination with trastuzumab and chemotherapy, for the adjuvant treatment of human epidermal growth factor receptor-2 positive (HER2+) lymph node positive eBC.

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Change to listing (Minor Submission)	QUADRIVALENT INFLUENZA VACCINE 0.5 mL pre-filled syringe Fluarix Tetra® GlaxoSmithKline Australia Pty Ltd	Influenza	To request an extension of the National Immunisation Program listing of the Fluarix® Tetra brand to include children aged 6 months to 3 years of age.
New listing (Minor Submission)	RITUXIMAB Solution for I.V. infusion 100 mg in 10 mL Solution for I.V. infusion 500 mg in 50 mL Truxima® Celltrion Healthcare Australia Pty. Ltd.	Non-Hodgkin lymphoma	To request a Section 100 (Efficient Funding of Chemotherapy) listing of a biosimilar rituximab for the treatment of CD20 positive B-cell non-Hodgkin lymphoma under the same conditions as the reference biologic.
New listing (Major Submission)	RIVAROXABAN Tablet 2.5 mg Xarelto® Bayer Australia Ltd	Coronary Artery Disease (CAD) and Peripheral Artery Disease (PAD)	To request an Authority Required (STREAMLINED) listing for treatment of patients at high risk of recurrent cardiovascular events in the stable phase of CAD and/or PAD.
New listing (Minor Submission)	SEVELAMER Tablet containing sevelamer carbonate 800 mg Sevelamer Dr Reddy's® Dr Reddy's	Hyperphosphataemia	To request Section 100 (Highly Specialised Drug Program) and Section 85 Authority Required (STREAMLINED) listings for the treatment of hyperphosphataemia in adult patients with chronic kidney disease who are on dialysis.

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New listing (Major Submission)	SODIUM PHENYLBUTYRATE Granules 483 mg (as sodium) per g, 174 g Pheburane® Orpharma Pty Ltd	Urea cycle disorders (UCD)	Resubmission to request an Authority Required listing for the treatment of patients with UCD.
New listing (Major Submission)	TEDUGLUTIDE Powder for injection 5 mg with diluent Revestive® Shire Australia Pty Limited	Short Bowel Syndrome (SBS)	Resubmission to request a Section 100 (Highly Specialised Drug) Authority Required listing for the treatment of SBS in patients who are dependent on parenteral nutrition for survival.
New listing (Major Submission)	TEZACAFTOR with IVACAFTOR Tablet containing tezacaftor 100 mg with ivacaftor 150 mg Symdeko® Vertex Pharmaceuticals (Australia) Pty Ltd	Cystic fibrosis (CF)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of CF in patients aged over 12 years: <ul style="list-style-type: none"> • who are homozygous for the <i>F508del</i> mutation in the CF transmembrane conductance regulator (CFTR) gene; or • who have at least one residual function (RF) mutation in the CFTR gene.
New listing (Minor Submission)	TIOTROPIUM Capsule containing powder for oral inhalation 13 microgram (for use in Zonda device) Braltus® TEVA Australia Pty Ltd	Chronic obstructive pulmonary disease (COPD)	To request a Restricted Benefit listing for the treatment of COPD.

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MARCH 2019 PBAC MEETING**

Closing date for consumer comments 13 February 2019

Submission type (new listing, change to listing)	Drug Name, form(s), strength(s) and Sponsor (Drug name, form, strength, Trade name®, Sponsor)	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.)
Other business (Minor Submission)	TIOTROPIUM Capsule containing powder for oral inhalation 18 micrograms (for use in HandiHaler) Spiriva® Boehringer-Ingelheim Pty Ltd	Chronic obstructive pulmonary disease (COPD)	To request that Spiriva and Braltus brands of tiotropium not be 'a' flagged.
Change to listing (Minor Submission)	TOCILIZUMAB Injection 162 mg in 0.9 mL single use pre-filled pen Injection 162 mg in 0.9 mL single use pre-filled syringe Actemra® Roche Products Pty Ltd	Polyarticular juvenile idiopathic arthritis (pJIA).	To request an extension of the current Authority Required listing of subcutaneous tocilizumab to include pJIA.
Change to listing (Minor Submission)	TOCILIZUMAB Injection 162 mg in 0.9 mL single use pre-filled pen Actemra® Roche Products Pty Ltd	Giant Cell Arteritis	Resubmission to request an Authority Required listing for the treatment of giant cell arteritis.

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Change to listing (Major Submission)	TOFACITINIB Tablet 5 mg Tablet 10 mg Xeljanz® Pfizer Australia Pty Ltd	Ulcerative Colitis (UC)	To request an Authority Required listing for the treatment of moderate to severe UC in adult patients who have had an inadequate response or failure of standard medical management (5-aminosalicylates [5-ASAs], thiopurines and/or a course of corticosteroids) according to the Mayo endoscopy score, or intolerance to these treatments.
New listing (Minor Submission)	TRASTUZUMAB Powder for I.V. infusion 150 mg Powder for I.V. infusion 440 mg with diluent Ogivri® Alphapharm Pty Ltd	Breast cancer Gastric cancer	To request a Section 100 (Efficient Funding of Chemotherapy) listing of a biosimilar trastuzumab under the same conditions as the reference biologic.
New listing (Minor Submission)	TRASTUZUMAB Powder for I.V. infusion 150 mg Ontruzant® Merck Sharp & Dohme (Australia) Pty Limited	Breast cancer Gastric cancer	To request a Section 100 (Efficient Funding of Chemotherapy) listing of a biosimilar trastuzumab under the same conditions as the reference biologic.

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Change to listing (Minor Submission)	TRIGLYCERIDES - MEDIUM CHAIN, FORMULA Oral liquid 500mL, 12 (Nutrini Peptisorb) Oral liquid 500 mL, 12 (Nutrini Peptisorb Energy) Nutrini Peptisorb® Nutrini Peptisorb Energy® Nutricia Australia Pty Limited	Dietary management of conditions requiring a source of medium chain triglycerides	To request a change to the pack size and maximum quantities of Nutrini Peptisorb and Nutrini Peptisorb Energy.
Sub-committee report (DUSC Analysis)	Bendamustine (Ribomustin®, Janssen-Cilag Pty Ltd)	Stage III or IV indolent CD20 positive non-Hodgkins lymphoma and Mantle cell lymphoma	To compare the predicted and actual utilisation of bendamustine for the treatment of lymphoma in the first 24 months of PBS listing.
Sub-committee report (DUSC Analysis)	Eculizumab (Soliris®, Alexion Pharmaceuticals Australasia Pty Ltd)	Atypical haemolytic uraemic syndrome	To complete a brief review to report on the number of initiating and prevalent patients, and the extent of continuation, stopping and restarting therapy.

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Matters relating to the Post-market Review of Pulmonary Arterial Hypertension (PAH) Medicines	Matters relating to the PBS review: Bosentan Ambrisentan Macitentan Epoprostenol Iloprost Sildenafil, tablet 20mg Tadalafil, tablet 20mg (56) Riociguat (all listed brands including generic versions)	Pulmonary Arterial Hypertension (PAH)	To consider the restriction amendments for PAH medicines as requested by the PBAC following consideration of the Post-market Review of PAH medicines in November 2018
Other business	PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® Merck Sharp and Dohme (Australia) Pty Ltd	First-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) expressing PD-L1 TPS>50%.	The Department is seeking the advice of the PBAC on the clinical and economic analyses for pembrolizumab when used for the first line treatment of patients with metastatic non-small cell lung cancer (NSCLC) expressing PD-L1 TPS > 50% as recommended for PBS listing in July 2018 in light of the availability of new clinical trial data.