

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

**Closing date for consumer comments 12 June 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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<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 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.)
Change to listing  Change to recommended listing  (Major Submission)	<b>AFLIBERCEPT</b>  Solution for intravitreal injection 4 mg in 100 microlitres (40 mg per mL) vial Solution for intravitreal injection 4 mg in 100 microlitres (40 mg per mL) pre-filled syringe  Eylea®  Bayer Australia Ltd	Subfoveal choroidal neovascularisation	To request an Authority Required listing for the treatment of patients with subfoveal choroidal neovascularisation secondary to pathologic myopia.
New listing  (Minor Submission)	<b>AMINO ACID FORMULA WITH VITAMINS AND MINERALS, LOW PHENYLALANINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID AND ARACHIDONIC ACID</b>  Sachets containing oral powder 12.5 g, 30 (PKU Explore 5) Sachets containing oral powder 25 g, 30 (PKU Explore 10)  PKU Explore®  Vitaflo Australia Pty Ltd	Phenylketonuria (PKU)	To request a Restricted Benefit listing for the dietary management of PKU.

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New listing (Major Submission)	APALUTAMIDE  Tablet 60 mg  Eryand®  Janssen-Cilag Pty Ltd	Castration resistant prostate cancer	Resubmission to request an Authority Required listing for the treatment of non-metastatic castration resistant prostate cancer in combination with androgen deprivation therapy.
Change to listing (Major Submission)	ATEZOLIZUMAB  Solution concentrate for I.V. infusion 1200 mg in 20 mL  Tecentriq®  Roche Products Pty Ltd	Small cell lung cancer	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first-line treatment of patients with extensive-stage small cell lung cancer.
New listing (Major Submission)	BEZLOTOXUMAB  Solution concentrate for I.V. infusion 1000 mg in 40 mL  Zinplava®  Merck Sharp & Dohme (Australia) Pty Ltd	Prevention of recurrent clostridium difficile infection (CDI)	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for prevention of recurrent CDI in patients with confirmed toxin B positive CDI and two or more risk factors for CDI recurrence.
Change to listing (Minor Submission)	BLINATUMOMAB  Powder for I.V. infusion 38.5 micrograms  Blincyto®  Amgen Australia Pty Limited	Acute lymphoblastic leukaemia (ALL)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of B-cell precursor ALL in patients with haematological complete remission with minimal residual disease following chemotherapy.

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Change to listing  (Major 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	To request an Authority Required (STREAMLINED) listing for use as first-line treatment of mild asthma.
Change to listing  (Major Submission)	<b>CABOZANTINIB</b>  Tablet 20 mg Tablet 40 mg Tablet 60 mg  Cabometyx®  Ipsen Pty Ltd	Hepatocellular carcinoma	To request an Authority Required (STREAMLINED) listing for the treatment of patients with hepatocellular carcinoma who have previously been treated with sorafenib for this condition.

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Change to recommended listing  (Minor Submission)	CARMELLOSE  Eye drops containing carmellose sodium 5 mg per mL, 10 mL  Evolve® carmellose  HYPROMELLOSE  Eye drops containing hypromellose 3 mg per mL, 10 mL  Evolve® hypromellose  Contact Lens Centre Australia Ltd	Severe dry eye syndrome	Resubmission to request an Authority Required (STREAMLINED) listing for treatment of severe dry eye syndrome.
New listing  (Minor Submission)	CINACALCET  Tablet 30 mg Tablet 60 mg Tablet 90 mg  Pharmacor Cinacalcet®  Pharmacor Pty Limited	Chronic kidney disease (CKD)	To request an Authority Required (STREAMLINED) listing of cinacalcet for the treatment of patients with secondary hyperparathyroidism in CKD.

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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 lower limb	Resubmission to request a Section 100 (Botulinum Toxin Program) Authority Required (STREAMLINED) listing for the treatment of patients with moderate to severe focal spasticity of the lower limb following stroke.
Change to listing  (Minor 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	Resubmission 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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Change to listing  (Major Submission)	DENOSUMAB  Injection 120 mg in 1.7 mL  Xgeva®  Amgen Australia Pty Ltd	Multiple myeloma	Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with multiple myeloma who have renal impairment.
New listing  (Major Submission)	DOLUTEGRAVIR WITH LAMIVUDINE  Tablet containing dolutegravir 50 mg (as sodium) with lamivudine 300 mg  Dovato®  ViiV Healthcare 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.
New listing  (Major Submission)	DUPILUMAB  Injection 300 mg in 2 mL single use pre-filled syringe  Dupixent®  sanofi-aventis Australia Pty Ltd	Atopic dermatitis	Resubmission to request an Authority Required listing for the treatment of chronic, moderate to severe, atopic dermatitis in patients who have had an inadequate response to topical therapies.

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New listing  (Major 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	Urothelial cancer	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of locally advanced or metastatic urothelial cancer after the failure of a prior platinum-based chemotherapy.
New listing  (Major 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.

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New listing  (Minor Submission)	ENOXAPARIN  Injection containing enoxaparin sodium 120 mg (12,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe Injection containing enoxaparin sodium 150 mg (15,000 I.U. anti-Xa) in 1 mL pre-filled syringe  Clexane Forte® Enoxaparin Winthrop® Clexane Forte Safety-Lock®  Sanofi-aventis Australia Pty Ltd	Deep vein thrombosis (DVT)	To request unrestricted benefit listings of two new strengths of enoxaparin pre-filled syringes.
Change to listing  (Major 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 and symptomatic for atherosclerotic cardiovascular disease and who are inadequately controlled on optimal doses of high potency statins and ezetimibe.

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New listing  (Minor Submission)	FERRIC DERISOMALTOSE  Injection 1000 mg (iron) in 10 mL Injection 500 mg (iron) in 5 mL  Monofer®  Pfizer Australia Pty Ltd	Iron deficiency anaemia	To request an unrestricted benefit listing for a new strength of ferric derisomaltose and to request a change in the maximum quantity and repeats for the currently listed 500 mg strength of ferric derisomaltose.
New listing  (Minor Submission)	FINGOLIMOD  Capsule 250 micrograms (as hydrochloride)  Gilenya®  Novartis Pharmaceuticals Australia Pty Ltd	Relapsing-remitting multiple sclerosis (RRMS)	To request an Authority Required listing of a new strength of fingolimod capsules for patients with RRMS who weigh 40kg or less, including paediatric patients.
New listing  (Minor Submission)	FLUTICASONE FUROATE  Powder for oral inhalation in breath actuated device containing fluticasone furoate 50 micrograms per dose, 30 doses  Arnuity Ellipta®  GlaxoSmithKline Australia Pty Ltd	Asthma	To request an Unrestricted Benefit listing for a new strength of fluticasone furoate.

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New listing  (Major Submission)	GALCANEZUMAB  Injection 120 mg in 1 mL single use pre-filled pen  Emgality®  Eli Lilly Australia Pty Ltd	Chronic migraine	To request an Authority Required (STREAMLINED) listing for the prophylactic treatment of patients with chronic migraine who have experienced inadequate response, intolerance or a contraindication to at least three prior preventive migraine medications.
New listing  (Minor Submission)  <i>Withdrawn</i>	GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS  Sachets containing oral powder 28g, 30  Tylactin Build 20®  Cortex Health Pty Ltd	Tyrosinaemia	To request a Restricted Benefit listing for the dietary management of patients with tyrosinaemia.
New listing  (Minor Submission)	GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS  Sachets containing oral powder 35 g, 30 (TYR Sphere 20)  TYR Sphere 20®  Vitaflo Australia 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)	GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID WITH LOW PHENYLALANINE  Oral liquid 250 mL, 18  PKU GMP <sup>ro</sup> LQ®  Nutricia Australia Pty Ltd	Phenylketonuria (PKU)	To request a Restricted Benefit listing for the dietary management of PKU.
New listing and change to listing (Major Submission)	INFLUENZA QUADRIVALENT ADJUVANTED VACCINE  Injection 0.5 mL  Flud® Quad  INFLUENZA TRIVALENT ADJUVANTED VACCINE  Injection 0.5 mL  Flud®  Seqirus (Australia) Pty Ltd	Prevention of seasonal influenza	To request National Immunisation Program (NIP) listing for the prevention of seasonal influenza in patients aged 65 years and over; and to request that the PBAC review the circumstances of the recommended NIP listing for Flud® influenza trivalent adjuvanted vaccine for the prevention of seasonal influenza in patients aged 65 years and over.
New listing (Major Submission)	INFLUENZA QUADRIVALENT VACCINE  Injection 0.5 mL  Vaxigrip Tetra™  sanofi-aventis Australia Pty Ltd	Prevention of seasonal influenza	To request listing on the National Immunisation Program (NIP) for the population already eligible for seasonal influenza vaccination with other brands of influenza vaccine and to extend the population eligible for seasonal influenza vaccination through the NIP to include all children aged 6 months to <5 years.

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New listing  (Major Submission)	LANADELUMAB  Solution for injection 300 mg in 2 mL  Takhzyro®  Shire Australia Pty Ltd	Hereditary angioedema	To request an Authority Required listing for the prevention of recurrent attacks of hereditary anioedema (C1-esterase-inhibitor deficiency or dysfunction) in patients aged 12 years and older for whom the use of danazol is not clinically appropriate or not effective.
Change to listing  (Minor 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.
New listing  (Major Submission)	LEUPRORELIN  Subcutaneous implant 3.6 mg (as acetate) in pre-filled syringe Subcutaneous implant 5 mg (as acetate) in pre-filled syringe  Lerin®  Sandoz Pty Ltd	Prostate cancer	To request a Restricted Benefit listing for the treatment of patients with locally advanced (Stage C) and metastatic (Stage D) prostate cancer.

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New listing  (Minor Submission)	LISDEXAMFETAMINE  Capsule containing lisdexamfetamine dimesilate 20 mg Capsule containing lisdexamfetamine dimesilate 40 mg Capsule containing lisdexamfetamine dimesilate 60 mg  Vyvanse®  Shire Australia Pty Ltd	Attention deficit hyperactivity disorder (ADHD)	To request Authority Required listings for three new strengths of lisdexamfetamine for the treatment of ADHD.
New listing  (Major Submission)	LUMACAFITOR WITH IVACAFITOR  Sachet containing granules, lumacaftor 100 mg with ivacaftor 125 mg Sachet containing granules, lumacaftor 150 mg with ivacaftor 188 mg  Orkambi®  Vertex Pharmaceuticals (Australia) Pty Ltd	Cystic fibrosis	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of patients aged 2 years or older who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator gene.
New listing  (Minor Submission)	MUPIROCIN  Nasal ointment 20 mg (as calcium) per gram, 5 g  Medsurge Mupirocin Nasal Ointment®  Medsurge Healthcare Pty Ltd	<i>Staphylococcus aureus</i> infection	To request an Authority Required (STREAMLINED) listing for a new pack size of mupirocin nasal ointment for the treatment of Aboriginal or Torres Strait Islander persons with <i>Staphylococcus aureus</i> (golden staph) infection of the nasal cavity.

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Change to listing  (Minor Submission)	NATALIZUMAB  Solution concentrate for I.V. infusion 300 mg in 15 mL  Tysabri®  Biogen Australia Pty Ltd	Relapsing-remitting multiple sclerosis (RRMS)	To request the removal of age restrictions from the existing listing for the treatment of RRMS to permit use of natalizumab in all ages.
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	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program), Authority Required (STREAMLINED) listing for the adjuvant treatment of patients who have had completely surgically resected Stage III or Stage IV malignant melanoma.
Change to listing  (Major Submission)	NUSINERSEN  Solution for injection 12 mg in 5 mL  Spinraza®  Biogen Australia Pty Ltd	Spinal muscular atrophy	To request 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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New listing  (Major Submission)	OBETICHOLIC ACID  Tablet 5 mg Tablet 10 mg  Ocaliva®  Emerge Health Pty Ltd	Primary biliary cholangitis	Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with primary biliary cholangitis.
Change to listing  (Major Submission)	OCTREOTIDE  Injection (modified release) 30 mg (as acetate), vial and diluent syringe  Sandostatin®  Novartis Pharmaceuticals Australia Pty Ltd	Non-functional neuroendocrine tumours of midgut or suspected midgut origin	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of unresectable locally advanced or metastatic, non-functional neuroendocrine tumours of midgut or suspected midgut origin.
Change to listing  (Major Submission)	OSIMERTINIB  Tablet 40 mg Tablet 80 mg  Tagrisso®  AstraZeneca Pty Ltd	Non-small cell lung cancer (NSCLC)	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.

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Change to listing  (Major Submission)	OXYCODONE  Tablet containing oxycodone hydrochloride 10 mg (controlled release) Tablet containing oxycodone hydrochloride 15 mg (controlled release) Tablet containing oxycodone hydrochloride 20 mg (controlled release) Tablet containing oxycodone hydrochloride 30 mg (controlled release) Tablet containing oxycodone hydrochloride 40 mg (controlled release) Tablet containing oxycodone hydrochloride 80 mg (controlled release)  OxyContin®  Mundipharma Pty Limited	Chronic severe disabling pain	Resubmission to request changes to the authority level and restriction for the existing a-flagged listings for controlled release oxycodone for chronic severe disabling pain to differentiate the brands that are intended to be crush-deterrent.
New listing  (Minor Submission)	OXYCODONE  Capsule containing oxycodone hydrochloride 5 mg, 10  OxyNorm®  Mundipharma Pty Limited	Severe disabling pain	To request a Restricted Benefit listing for a new pack size of oxycodone.

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Change to listing  (Major Submission)	PEMBROLIZUMAB  Solution concentrate for I.V. infusion 100 mg in 4 mL  Keytruda®  Merck Sharp & Dohme (Australia) Pty Ltd	Melanoma	Resubmission to request Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the adjuvant treatment of patients who have had completely surgically resected Stage III malignant melanoma.
Change to listing  (Major Submission)	PEMBROLIZUMAB  Solution concentrate for I.V. infusion 100 mg in 4 mL  Keytruda®  Merck Sharp & Dohme (Australia) Pty Ltd	Non-small cell lung cancer (NSCLC)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing, in combination with platinum chemotherapy and pemetrexed, for the first-line treatment of Stage IV non-squamous non-small cell lung cancer.
New listing  (Major Submission)	PLITIDEPSIN  Powder for I.V. infusion 2 mg with 4 mL solvent  Aplidin®  Specialised Therapeutics Pharma Pty Ltd	Multiple myeloma	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required listing in combination with dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who meet certain conditions.

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Change to listing  (Major Submission)	POMALIDOMIDE  Capsule 3 mg Capsule 4 mg  Pomalyst®  Celgene Pty Ltd	Multiple myeloma	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 recommended listing  (Minor Submission)	RAMUCIRUMAB  100 mg in 10 mL vial, 500 mg in 50 mL vial  Cyramza®  Eli Lilly Australia Pty Ltd	Advanced or metastatic gastric or gastro-oesophageal junction adenocarcinoma	Resubmission to request reconsideration of the recommended Authority Required (STREAMLINED) listing in combination with paclitaxel for treatment of advanced or metastatic gastric or gastro-oesophageal junction adenocarcinoma. Ramucirumab was recommended by the PBAC at its March 2018 meeting.
New listing  (Minor Submission)	REGORAFENIB  Tablet 40 mg (as monohydrate)  Stivarga®  Bayer Australia Ltd	Hepatocellular carcinoma (HCC)	Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with unresectable HCC who have progressed on prior tyrosine kinase inhibitor treatment.
Change to listing  (Minor Submission)	RIFAXIMIN  Tablet 550 mg  Xifaxan®  Norgine Pty Ltd	Prevention of hepatic encephalopathy	To request a change to the existing listing from Authority Required (Telephone) to Authority Required (STREAMLINED).

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New listing  (Major Submission)	RISANKIZUMAB  Injection 75 mg in 0.83 mL pre-filled syringe  Skyrizi®  AbbVie Pty Ltd	Chronic plaque psoriasis	To request an Authority Required listing for the treatment of severe chronic plaque psoriasis.
New listing  (Major Submission)	ROMOSOZUMAB  Injection 105 mg in 1.17 mL single use pre-filled syringe Injection 105 mg in 1.17 mL single use pre-filled pen  Evenity®  Amgen Australia Pty Ltd	Severe osteoporosis	Resubmission to request an Authority Required listing for the treatment of severe osteoporosis.
New listing  (Minor Submission)	SAPROPTERIN  Powder for oral liquid 100 mg (as dihydrochloride), Powder for oral liquid 500 mg (as dihydrochloride)  Kuvan®  BioMarin Pharmaceutical Australia Pty Ltd	Hyperphenylalaninaemia (HPA)	To request the Authority Required listing of two new forms of sapropterin for the treatment of HPA in patients with tetrahydrobiopterin (BH4) deficiency; and in patients with phenylketonuria (PKU).

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Change to listing  (Minor Submission)	SAPROPTERIN  Tablet (soluble) containing sapropterin dihydrochloride 100 mg  Kuvan®  BioMarin Pharmaceutical Australia Pty Ltd	Hyperphenylalaninaemia (HPA)	To request a change to the existing listing from Authority Required (Written) to Authority Required (Telephone) for the treatment of HPA in patients with tetrahydrobiopterin (BH4) deficiency.
New listing  (Minor Submission)	SODIUM PHENYLBUTYRATE  Granules 483 mg (as sodium) per g, 174 g  Pheburane®  Orpharma Pty Ltd	Urea cycle disorder (UCD)	Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with UCD.
New listing  (Minor Submission)	TRASTUZUMAB  Powder for I.V. infusion 150 mg  Herzuma®  Celltrion Healthcare 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.
New listing  (Minor Submission)	TRASTUZUMAB  Powder for I.V. infusion 60 mg Powder for I.V. infusion 150 mg Powder for I.V. infusion 420 mg  Kanjinti®  Amgen 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.

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Change to listing  (Minor Submission)	TYROSINE WITH CARBOHYDRATE  Sachets of oral powder 4 g containing 1 g tyrosine, 30 (Tyrosine 1000)  Tyrosine 1000®  Vitaflo Australia Pty Ltd	Phenylketonuria (PKU)	To request a change to the existing listing to reflect a change in the recommended age indication from "suitable from birth" to "suitable from 3 years of age" due to product formulation changes.
Sub-committee report  (DUSC Analysis)	ARMODAFINIL  Nuvigil®  Teva Pharma Australia Pty Limited	Narcolepsy	To compare the predicted and actual use of armodafinil for the treatment of narcolepsy since PBS listing for this indication. Use of dexamfetamine and modafinil for this indication will also be reported.
Sub-committee report  (DUSC Analysis)	GONADOTROPHIN-RELEASING HORMONE (GnRH) AGONISTS:  GOSERELIN Zoladex®, AstraZeneca Pty Ltd  GOSERELIN AND BICALUTAMIDE ZolaCos®, AstraZeneca Pty Ltd  LEUPRORELIN Lucrin®, AbbVie Pty Ltd Eligard®, Mundipharma Pty Limited  NAFARELIN Synarel®, Pfizer Australia Pty Ltd  TRIPTORELIN Diphereline®, Ipsen Pty Ltd	Carcinoma of the prostate, central precocious puberty, breast cancer, endometriosis, and anticipated premature ovarian failure.	To review the use of gonadotrophin-releasing hormone (GnRH) agonists for the treatment of carcinoma of the prostate, central precocious puberty, breast cancer, endometriosis, and anticipated premature ovarian failure. The analysis will not include use of these medicines for in-vitro fertilisation (IVF).

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Sub-committee report (DUSC Analysis)	SAPROPTERIN Kuvan® BioMarin Pharmaceutical Australia Pty Ltd	Hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency	To compare the predicted and actual use of sapropterin for the treatment of HPA due to BH4 deficiency since PBS listing for this indication.
Cost-effectiveness review of pneumococcal vaccines for the National Immunisation Program (NIP).	PNEUMOCOCCAL VACCINES Pneumovax 23® Seqirus Australia Pty Ltd  Prevenar 13® Pfizer Australia Pty Ltd	Vaccines for the prevention of pneumococcal disease	To consider the eligible populations for vaccination with a 23-valent pneumococcal polysaccharide vaccine (23vPPV) and or 13-valent pneumococcal conjugate vaccine (13vPCV) via the National Immunisation Program (NIP).