PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
NOVEMBER 2020 PBAC MEETING

Closing date for consumer comments 7 October 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 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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New listing (Minor Submission)	ADALIMUMAB Injection 40 mg pre-filled pen Injection 40 mg pre-filled syringe Injection 40 mg vial Idacio® Fresenius Kabi Australia Pty Limited	Severe Crohn disease; moderate to severe ulcerative colitis; severe active juvenile idiopathic arthritis; complex refractory fistulising Crohn disease; severe active rheumatoid arthritis; severe psoriatic arthritis; ankylosing spondylitis; severe chronic plaque psoriasis; moderate to severe hidradenitis suppurativa	To request an Authority Required (STREAMLINED) listing of a new biosimilar adalimumab under the same conditions as the reference biologic.
Change to listing (Minor Submission)	ADALIMUMAB Injection 40 mg pre-filled syringe Injection 40 mg auto-injector Hadlima® Merck Sharp & Dohme (Australia) Pty Ltd	Severe Crohn disease; complex refractory fistulising Crohn disease; moderate to severe ulcerative colitis; severe active juvenile idiopathic arthritis; adult patients with a history of juvenile idiopathic arthritis; severe psoriatic arthritis; ankylosing spondylitis; severe chronic plaque psoriasis; severe active rheumatoid arthritis	To request an Authority Required (STREAMLINED) listing for the biosimilar in the continuing treatment phase; to request an Authority Required (telephone) for the biosimilar in the initial treatment phase; and to request that use of the biosimilar not count as treatment failure.
New listing (Minor Submission)	ADRENALINE I.M. injection 150 micrograms in 0.3 mL single dose syringe auto-injector I.M. injection 300 micrograms in 0.3 mL single dose syringe auto-injector I.M. injection 500 micrograms in 0.3 mL single dose syringe auto-injector Anapen® Allergy Concepts Pty Ltd	Acute allergic reaction with anaphylaxis	To request the Authority Required listing of an alternative brand of adrenaline auto-injector under the same conditions as other brands of adrenaline currently listed on the PBS and to request the Authority Required listing of a new strength of adrenaline auto-injector.

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New listing (Minor Submission)	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN Sachets containing oral powder 24 g Sachets containing oral powder 25 g GA Gel® GA Express 15® Vitaflo Australia Pty Limited	Pyridoxine dependent epilepsy	To request a Restricted Benefit listing for the management of pyridoxine dependent epilepsy.
New listing (Major Submission)	APALUTAMIDE Tablet 60 mg Erlyand® Janssen-Cilag Pty Ltd	Prostate cancer	Resubmission to request an Authority Required (Telephone) listing for the treatment of castration resistant prostate cancer with no distant metastasis on conventional imaging.
Change to listing (Minor Submission)	APOMORPHINE Solution for subcutaneous infusion containing apomorphine hydrochloride hemihydrate 50 mg in 10 mL pre-filled syringe Movapo PFS® Stada Pharmaceuticals Australia Pty Limited	Parkinson's disease	To request General Schedule, Authority Required (STREAMLINED) listing for the continuing treatment of Parkinson's disease following initiation with the current Section 100 (Highly Specialised Drugs Program) listings.

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New listing (Major Submission)	BECLOMETASONE DIPROPIONATE + FORMOTEROL FUMARATE DIHYDRATE + GYLCOPYRRONIUM Pressurised inhalation containing beclometasone dipropionate 100 micrograms with formoterol fumarate dihydrate 6 micrograms and glycopyrronium 10 micrograms (as bromide) per dose, 120 doses Trimbow® Chiesi Australia Pty Ltd	Chronic obstructive pulmonary disease (COPD)	To request an Authority Required (STREAMLINED) listing for maintenance treatment of moderate to severe COPD.
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 MVASI® Amgen Australia Pty Limited	Metastatic colorectal cancer (mCRC); advanced stage IIIB, IIIC or stage IV epithelial ovarian, fallopian tube, or primary peritoneal cancer; advanced carcinoma of the cervix; stage IV (metastatic) non-small cell lung cancer (NSCLC); relapsed or recurrent glioblastoma	To request Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing of a new biosimilar bevacizumab under the same conditions as the reference biologic.
Change to listing (Major Submission)	CABOZANTINIB Tablet 20 mg Tablet 40 mg Tablet 60 mg Cabometyx® Ipsen Pty Ltd	Renal cell carcinoma (RCC)	Resubmission to request an extension to the current Authority Required (STREAMLINED) listing for the treatment of Stage IV clear cell variant RCC to include patients who have not been previously treated with a tyrosine kinase inhibitor (TKI).

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NOVEMBER 2020 PBAC MEETING

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New listing (Major Submission)	CARIPRAZINE Capsule 1.5 mg Capsule 3 mg Capsule 4.5 mg Capsule 6 mg Reagila® Seqirus (Australia) Pty Ltd	Schizophrenia	To request an Authority Required (STREAMLINED) listing for the treatment of schizophrenia.
New listing (Major Submission)	CEMIPLIMAB Solution for IV infusion 350 mg in 7 mL Libtayo® Sanofi-Aventis Australia Pty Ltd	Squamous cell carcinoma (SCC)	To request Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of metastatic or locally advanced cutaneous SCC in patients who are not candidates for curative surgery or curative radiation.
New listing (Major Submission)	CRISABOROLE Ointment 2%, 30 g Ointment 2%, 60 g Staquis® Pfizer Australia Pty Ltd	Atopic dermatitis	Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of mild to moderate atopic dermatitis.
Change to listing (Major Submission)	DAPAGLIFLOZIN Tablet 10 mg Forxiga® AstraZeneca Pty Ltd	Heart failure	To request an extension of the current Authority Required (STREAMLINED) listing to include the treatment of heart failure in patients with reduced ejection fraction.

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Closing date for consumer comments 7 OCT 2020

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New listing (Minor Submission)	DEFERASIROX Dispersible tablet 125 mg Dispersible tablet 250 mg Dispersible tablet 500 mg Deferasirox Juno® Juno Pharmaceuticals Pty Ltd	Chronic iron overload	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for a new form of deferasirox for the treatment of chronic iron overload.
Change to listing (Major Submission)	DUPILUMAB Injection 200 mg in 1.14 mL single dose pre-filled syringe Injection 300 mg in 2 mL single dose pre-filled syringe Dupixent® Sanofi-Aventis Australia Pty Ltd	Asthma	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of severe uncontrolled asthma.
New listing (Other)	DUPILUMAB Injection 200 mg in 1.14 mL single use pre-filled syringe Injection 300 mg in 2 mL single use pre-filled syringe Dupixent® Sanofi-Aventis Australia Pty Ltd	Atopic dermatitis	To request that the PBAC review a revised proposal following the March 2020 recommendation for dupliumab for the treatment of patients with chronic severe atopic dermatitis who have had an inadequate response to topical therapies.

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Change to 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	Small cell lung cancer (SCLC)	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing in combination with etoposide and platinum-based chemotherapy for the first-line treatment of extensive-stage SCLC.
Change to listing (Major Submission)	ECULIZUMAB Solution concentrate for I.V. infusion 300 mg in 30 mL Soliris® Alexion Pharmaceuticals Australasia Pty Ltd	Neuromyelitis optica spectrum disorder (NMOSD)	To request an Authority Required (Written) listing for the treatment of patients with relapsing NMOSD who are anti-aquaporin-4 (AQP4) antibody positive.
New listing (Major Submission)	ELOTUZUMAB Powder for IV infusion 300 mg Powder for IV infusion 400 mg Empliciti® Bristol-Myers Squibb Australia Pty Ltd	Multiple myeloma	To request Section 100 (Efficient Funding of Chemotherapy) Authority Required (Telephone) listing in combination with lenalidomide and dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
NOVEMBER 2020 PBAC MEETING

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Change to listing (Minor Submission)	EVOLOCUMAB Injection 140 mg in 1 mL single use pre-filled pen Injection 420 mg in 3.5 mL single use pre-filled cartridge Repatha® Amgen Australia Pty Limited	Familial heterozygous hypercholesterolaemia; Non-familial hypercholesterolaemia; Familial homozygous hypercholesterolaemia	To request an amendment to the Authority Required listing to allow general practitioners to initiate treatment in consultation with a specialist.
New listing (Major Submission) WITHDRAWN	FILGOTINIB Tablet 100 mg Tablet 200 mg Jyseleca® Gilead Sciences Pty Ltd	Rheumatoid arthritis	To request an Authority Required (Written) listing for the treatment of severe active rheumatoid arthritis.
New listing (Minor Submission)	FLUOCINOLONE ACETONIDE Intravitreal injection 190 micrograms Iluvien® Specialised Therapeutics Alim Pty Ltd	Diabetic macular oedema	Resubmission to request an amendment to the PBAC's previously recommended equi-effective doses for fluocinolone acetonide and dexamethasone.
New listing (Major Submission)	GALCANEZUMAB Injection 120 mg in 1 mL pre-filled pen Emgality® Eli Lilly Australia Pty Ltd	Episodic migraine	To request an Authority Required (STREAMLINED) listing for the treatment of adult patients with treatment-resistant episodic migraine.

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New listing (Minor Submission)	GALCANEZUMAB Injection 120 mg in 1 mL pre-filled pen Emgality® Eli Lilly Australia Pty Ltd	Chronic migraine	Resubmission 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.
Change to listing (Minor Submission)	GLECAPREVIR + PIBRENTASVIR Tablet containing 100 mg glecaprevir with 40 mg pibrentasvir Maviret® AbbVie Pty Ltd	Chronic hepatitis C infection	To request an amendment to the Section 100 (Highly Specialised Drugs Program) and General Schedule Authority Required listings to reduce the duration of treatment from 12 weeks to 8 weeks for treatment naïve patients with chronic hepatitis C with compensated cirrhosis.
Change to listing (Major Submission)	GUSELKUMAB Injection 100 mg in 1 mL single use pre-filled syringe Injection 100 mg in 1 mL single use pre-filled pen Tremfya® Janssen-Cilag Pty Ltd	Psoriatic arthritis	To request an Authority Required (Written) listing for the treatment of adult patients with severe psoriatic arthritis who have had an inadequate response to methotrexate and sulfasalazine or leflunomide.

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New listing (Minor Submission)	HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE Oral liquid 250 mL, 30 KetoVie 4:1® KetoVie 3:1® KetoVie Peptide 4:1® Cortex Health Pty Ltd	Ketogenic diet	To request a Restricted Benefit listing for KetoVie 4:1 and 3:1 and an Authority Required (STREAMLINED) listing for KetoVie Peptide 4:1 as part of a ketogenic diet.
New listing (Minor Submission)	IBRUTINIB Tablet 140 mg Tablet 280 mg Tablet 420 mg Tablet 560 mg Imbruvica® Janssen-Cilag Pty Ltd	Chronic lymphocytic leukaemia (CLL); small lymphocytic lymphoma (SLL); mantle cell lymphoma	To request an Authority Required listing of ibrutinib tablet under the same conditions as the already listed capsule.
New listing (Major Submission)	INFLIXIMAB Injection 120 mg in 1 mL pre-filled syringe Injection 120 mg in 1 mL pre-filled pen Remsima® SC Celltrion Healthcare Australia Pty Ltd	Rheumatoid arthritis Ankylosing spondylitis Psoriatic arthritis Chronic plaque psoriasis Crohn's disease Complex refractory fistulising Crohn's disease Ulcerative colitis	To request Section 100 (Highly Specialised Drugs Program) and Authority Required listings under the same conditions as infliximab powder for I.V. infusion 100 mg.

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New listing (Major Submission)	IXAZOMIB Capsule 2.3 mg Capsule 3 mg Capsule 4 mg Ninlaro® Takeda Pharmaceuticals Australia Pty Ltd	Multiple myeloma	To request Section 100 (Highly Specialised Drugs Program) Authority Required (Telephone) listing in combination with lenalidomide and dexamethasone for patients with relapsed or refractory multiple myeloma.
New listing (Major Submission)	LAROTRECTINIB Capsule 25 mg Capsule 100 mg Oral solution 20 mg per mL, 100 mL Vitrakvi® Bayer Australia Ltd	Solid tumours harbouring neurotrophic receptor tyrosine kinase (NTRK) gene fusions	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of locally advanced or metastatic solid tumours harbouring NTRK gene fusions.
New listing (Major Submission)	MENINGOCOCCAL POLYSACCHARIDE SEROGROUPS A, C, W-135 AND Y CONJUGATE VACCINE Injection 0.5 mL MenQuadfi® Sanofi-Aventis Australia Pty Ltd	Prevention of meningococcal disease	To request National Immunisation Program (NIP) listing for the prevention of meningococcal disease in toddler and adolescent populations.

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New listing (Minor Submission)	MESALAZINE Tablet 1600 mg Asacol® Chiesi Australia Pty Ltd	Ulcerative colitis	To request a Restricted Benefit listing of mesalazine for the treatment of mild to moderate ulcerative colitis and maintenance of remission in adults.
New listing (Minor Submission)	MOGAMULIZUMAB Solution concentrate for I.V. infusion 20 mg in 5 mL Poteligeo® Kyowa Kirin Australia Pty Ltd	Cutaneous T-Cell Lymphoma (CTCL)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (Written) listing for patients with relapsed or refractory CTCL who have previously been treated with at least one prior systemic therapy.

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Change to listing (Major Submission)	NIVOLUMAB IPILIMUMAB 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: Injection concentrate for I.V. infusion 50 mg in 10 mL Yervoy® Bristol-Myers Squibb Australia Pty Ltd	Non-small cell lung cancer (NSCLC)	To request Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing in combination with two cycles of chemotherapy for the first-line treatment of patients with Stage IV (metastatic) NSCLC.
Change to listing (Major Submission)	NUSINERSEN Solution for injection 12 mg in 5 mL Spinraza® Biogen Australia Pty Ltd	Spinal muscular atrophy (SMA)	Resubmission to request an extension to the current Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing to include the treatment of adults with SMA.

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New listing (Major Submission)	OBETICHOLIC ACID Tablet 5 mg Tablet 10 mg Ocaliva® Chiesi Australia Pty Ltd	Primary biliary cholangitis	Resubmission to request an Authority Required (Written) listing for the treatment of primary biliary cholangitis.
New listing (Major Submission)	ONASEMNOGENE ABEPARVOVEC Solution for injection, customised based on patient weight Zolgensma® Novartis Pharmaceuticals Australia Pty Ltd	Spinal muscular atrophy (SMA)	Submission to request an Authority Required (Written) listing for the treatment of paediatric patients less than 2 years of age with Type 1 SMA.
New listing (Minor Submission)	PANCREATIC EXTRACT Capsule (containing enteric coated minimicrospheres) providing not less than 20,000 BP units of lipase activity Capsule (containing enteric coated minimicrospheres) providing not less than 35,000 BP units of lipase activity Creon® Mylan Health Pty Ltd	Pancreatic exocrine insufficiency	To request an Unrestricted Benefit listing under the same conditions as the already listed strengths.

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New listing (Major Submission)	PATIROMER Sachet, 8.4 g powder for oral liquid Sachet, 16.8 g powder for oral liquid Veltassa® Vifor Pharma Pty Ltd	Hyperkalaemia	Resubmission to request an Authority Required (Telephone) 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.
Change to listing (Major Submission)	PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® Merck Sharp & Dohme (Australia) Pty Ltd	Squamous cell carcinoma of the head and neck (SCCHN)	To request Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the first line treatment of recurrent or metastatic SCCHN.
Change to listing (Major Submission)	PROGESTERONE Capsule 200 mg Utrogestan® Besins Healthcare Australia Pty Ltd	Prevention of preterm birth	To request an extension of the current Authority Required (STREAMLINED) listing to include the prevention of preterm birth in women at risk.
Change to listing (Major Submission)	PROGESTERONE Pessary 200 mg Oripro® Orion Laboratories Pty Ltd	Prevention of preterm birth	To request an extension of the current Authority Required (STREAMLINED) listing to include the prevention of preterm birth in women at risk.

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Change to listing (Minor Submission)	RIBOCICLIB Tablet 200 mg Kisqali® Novartis Pharmaceuticals Australia Pty Ltd	Locally advanced or metastatic breast cancer	Resubmission 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.
Change to listing (Major Submission)	SACUBITRIL with VALSARTAN Tablet containing sacubitril 24.3 mg + valsartan 25.7 mg Tablet containing sacubitril 48.6 mg + valsartan 51.4 mg Tablet containing sacubitril 97.2 mg + valsartan 102.8 mg Entresto® Novartis Pharmaceuticals Australia Pty Ltd	Heart failure	To request changes to the current Authority Required (STREAMLINED) listing for patients with chronic heart failure with reduced ejection fraction (HF-rEF) to include a broader population of patients.
Change to listing (Minor Submission)	SAPROPTERIN Powder for oral solution 500 mg Tablet (soluble) 100 mg Kuvan® Biomarin Pharmaceutical Australia Pty Ltd	Maternal phenylketonuria (MPKU)	Resubmission to request an Authority Required listing in combination with a Phe-restricted diet for the treatment of MPKU where a Phe-restricted diet does not adequately reduce blood Phe levels.

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Change to listing (Major Submission)	SECUKINUMAB Injection 150 mg in 1 mL pre-filled pen Cosentyx® Novartis Pharmaceuticals Australia Pty Ltd	Non-radiographic axial spondyloarthritis (nr-axSpA)	To request an Authority Required (Written) listing for the treatment of nr-axSpA.
Change to listing (Major and Minor Submissions)	TOFACITINIB Tablet 5 mg Tablet 10 mg Xeljanz® Pfizer Australia Pty Ltd	Ulcerative colitis and other listed indications	Resubmission to request an Authority Required (Written) listing for the treatment of moderate to severe ulcerative colitis and separate submission to consider interchangeability advice.
Change to listing (Minor Submission)	UPADACITINIB Tablet 15 mg Rinvoq® Abbvie Pty Ltd	Severe rheumatoid arthritis	Resubmission to request review of the statistical basis upon which the claim of superior effectiveness versus adalimumab for the treatment of patients with severe active RA was not accepted.
New listing (Major Submission)	VEDOLIZUMAB Injection 108 mg in 0.68 mL pre-filled syringe Injection 108 mg in 0.68 mL pre-filled pen Entyvio® Takeda Pharmaceuticals Australia Pty Ltd	Ulcerative colitis Crohn's disease	To request Authority Required listings under the same conditions as vedolizumab powder for injection 300 mg.

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Sub-committee report (DUSC Analysis)	ADRENALINE I.M. injection 150 micrograms in 0.3 mL single dose syringe auto-injector I.M. injection 300 microgram in 0.3 mL single dose syringe auto-injector Epipen®, Adrenaline Mylan® Alphapharm Pty Ltd	Treatment of allergic reaction with anaphylaxis	To assess the utilisation of PBS listed adrenaline for the treatment of allergic reaction with anaphylaxis.
Sub-committee report (DUSC Analysis)	ALECTINIB Capsule 150 mg Alecensa® Roche Products Pty Ltd	Treatment of non-small cell lung cancer (NSCLC)	To compare the predicted and actual utilisation of alectinib for the treatment of NSCLC since PBS listing.
Sub-committee report (DUSC Analysis)	DENOSUMAB Injection 120 mg in 1.7 mL Xgeva® Amgen Australia Pty Ltd	Treatment of osteoporosis	To assess the utilisation of PBS listed denosumab for the treatment of osteoporosis.
Sub-committee report (DUSC Analysis)	ECULIZUMAB Solution concentrate for I.V. infusion 300mg in 30 mL Soliris® Alexion Pharmaceuticals Australasia Pty Ltd	Treatment of atypical haemolytic uraemic syndrome (aHUS)	To assess the utilisation of PBS listed eculizumab for the treatment of aHUS.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
NOVEMBER 2020 PBAC MEETING

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Sub-committee report (DUSC Analysis)	IBRUTINIB Capsule 140 mg Imbruvia® Janssen-Cilag Pty Ltd	Treatment of chronic lymphocytic leukaemia (CLL) and small lymphocytic lymphoma (SLL)	To compare the predicted and actual utilisation of ibrutinib for the treatment of CLL and SLL since PBS listing.
Sub-committee report (DUSC Analysis)	OCRELIZUMAB Solution concentrate for I.V. infusion 300 mg in 10 mL Ocrevus® Roche Products Pty Ltd	Treatment of relapsing-remitting multiple sclerosis (RRMS).	To compare the predicted and actual utilisation of ocrelizumab for the treatment of RRMS since PBS listing.