PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
NOVEMBER 2017 PBAC MEETING

Closing date for consumer comments 4 October 2017

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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Change to listing (Minor Submission)	1) MEDIUM CHAIN TRIGLYCERIDES 2) TRIGLYCERIDES LONG CHAIN 1) Oral liquid 225 mL (betaquik) 2) Oral liquid 225 mL (carbzero) 1) Betaquik 2) Carbzero Vitaflo Australia Pty Ltd	1) Ketogenic diet; dietary management of conditions requiring a source of medium chain triglycerides 2) Ketogenic diet	To advise the PBAC of a change to the formulation and request a change in the pack size and maximum quantity of Betaquik and Carbzero.
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	Familial hypercholesterolaemia and clinical atherosclerotic cardiovascular disease	To request an Authority Required listing for the treatment of patients with familial heterozygous hypercholesterolaemia and clinical atherosclerotic cardiovascular disease.
New listing (Minor Submission)	AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS, WITHOUT PHENYLALANINE Oral powder 400 g (PKU Start) PKU Start® Vitaflo Australia Pty Ltd	Phenylketonuria	To request a Restricted Benefit listing for the dietary management of patients with phenylketonuria.

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New listing (Major Submission)	APREMILAST Tablet 30 mg Pack containing 4 tablets of 10 mg , 4 tablets of 20 mg and 19 tablets of 30 mg Otezla® Celgene Pty Ltd	Moderate to severe plaque psoriasis	Resubmission to request a Restricted Benefit listing for treatment of patients with moderate to severe plaque psoriasis.
New listing (Minor Submission)	ARGININE Tablet 500 mg Arginine Easy® Orpharma Pty Ltd	Urea cycle disorders (UCD)	To request a Restricted Benefit listing for the treatment of UCD.
New listing (Major Submission)	ATEZOLIZUMAB Solution concentrate for I.V. infusion 1200 mg in 20 mL Tecentriq® Roche Products Pty Ltd	Non-small cell lung cancer (NSCLC)	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of locally advanced (stage IIIB) or metastatic (stage IV) NSCLC with progression on or after prior chemotherapy.

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New listing (Minor Submission)	BARICITINIB Tablet 2 mg Tablet 4 mg Olumiant® Eli Lilly Australia Pty Ltd	Severe active rheumatoid arthritis (RA)	Resubmission to request an Authority Required listing for the treatment of severe active RA under certain conditions.
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 Clostridium difficile infection (CDI) recurrence	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing to prevent recurrence of CDI, as an add-on to antibiotic treatment.
Change to listing (Minor Submission) WITHDRAWN	BLINATUMOMAB Powder for I.V. infusion 38.5 micrograms Blincyto® Amgen Australia Pty Ltd	Relapsed or refractory acute lymphoblastic leukemia	To request that the current Section 100 (Efficient Funding of Chemotherapy) supply arrangements be amended to Section 100 (Highly Specialised Drugs).

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New listing (Minor Submission)	BRIVARACETAM Tablet 25 mg Table 50 mg Tablet 75 mg Tablet 100 mg Oral suspension 10 mg per mL, 300 mL Briviact® UCB Australia Pty Ltd	Epilepsy	Resubmission to request Authority Required (STREAMLINED) listing for the treatment of intractable partial onset epileptic seizures.
New listing (Minor Submission)	BUDESONIDE WITH EFORMOTEROL Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with eformoterol fumarate dihydrate 6 micrograms per dose, 120 doses Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with eformoterol fumarate dihydrate 12 micrograms per dose, 120 doses DuoResp® Spiromax® Teva Pharma Australia Pty Limited	Asthma and chronic obstructive pulmonary disease (COPD)	Resubmission to request a Restricted Benefit listing for a new brand of budesonide with eformoterol (DuoResp® Spiromax®) for the treatment of patients with asthma and COPD aged 18 years and over.

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New listing (Major Submission)	BUDESONIDE Capsule (modified release) 3 mg Entocort® Emerge Health Pty Ltd	Crohn disease	To request an Authority Required listing for the treatment of patients with mild to moderate Crohn disease affecting the ileum and/or the ascending colon who meet certain criteria.
Change to recommended listing (Major Submission)	CANAKINUMAB Powder for injection 150 mg with solvent Solution for injection 150 mg in 1 mL Ilaris® Novartis Pharmaceuticals Australia Pty Ltd	Cryopyrin associated periodic syndromes (CAPS)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of patients with moderate to severe CAPS.
New listing (Major Submission)	CLADRIBINE Tablet 10 mg Mavenclad® Merck Serono Australia Pty Ltd	Relapsing-remitting multiple sclerosis (RRMS)	Resubmission to request an Authority Required listing for the treatment of RRMS.
Change to listing (Major Submission)	CRIZOTINIB Capsule 200 mg Capsule 250 mg Xalkori® Pfizer Australia Pty Ltd	Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) with a ROS1 gene rearrangement confirmed by fluorescent in situ hybridisation (FISH) testing	To request an Authority Required listing for the treatment of patients with Stage IIIB (locally advanced) or Stage IV (metastatic) NSCLC with a ROS1 gene rearrangement confirmed by FISH testing, in patients who have failed at least one treatment with platinum-based chemotherapy.

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New listing (Minor Submission)	1) DAPAGLIFLOZIN 2) DAPAGLIFLOZIN WITH METFORMIN 3) DAPAGLIFLOZIN WITH SAXAGLIPTIN 1) Tablet 10 mg (as propanediol monohydrate) 2) Tablet (modified release) containing 5 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 500 mg metformin hydrochloride Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride 3) Tablet containing 10 mg dapagliflozin (as propanediol monohydrate) with 5 mg saxagliptin 1) Forziga® 2) Xigduo® XR 3) Qtern® AstraZeneca Pty Ltd	Type 2 diabetes mellitus (T2DM)	Resubmission to request an Authority Required (STREAMLINED) listing for dapagliflozin in combination with a dipeptidyl peptidase 4 (DPP4) inhibitor and metformin for the treatment of T2DM.

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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	Relapsed/refractory multiple myeloma	To request an Authority Required listing, in combination with bortezomib or lenalidomide, for the treatment of relapsed or refractory multiple myeloma in patients who have progressive disease after at least one prior therapy.
New listing (Minor Submission)	DEFERIPRONE Tablet 1000 mg Ferriprox® Apotex Pty Ltd	Iron overload	To request an Authority Required (STREAMLINED) listing of new form of deferiprone.
Change to listing (Major Submission)	DEXAMETHASONE Intravitreal injection 700 micrograms Ozdurex® Allergan Australia Pty Ltd	Non-infectious uveitis (inflammatory disease of the eye)	To request an Authority Required listing for the treatment of non-infectious uveitis affecting the posterior segment of the eye.

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New 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 metformin or metformin and a sulfonylurea, for the treatment of T2DM.
New listing (Major Submission)	EMPAGLIFLOZIN WITH LINAGLIPTIN Tablet containing 10 mg empagliflozin with 5 mg linagliptin Tablet containing 25 mg empagliflozin with 5 mg linagliptin Glyxambi® Boehringer Ingelheim Pty Limited	Type 2 diabetes mellitus (T2DM)	Resubmission to request an Authority Required (STREAMLINED) listing for use in combination with metformin for the treatment of T2DM.

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Change to listing (Minor Submission)	1) EMPAGLIFLOZIN 2) EMPAGLIFLOZIN WITH METFORMIN 3) LINAGLIPTIN 4) LINAGLIPTIN WITH METFORMIN 1) Tablet 10mg Tablet 25 mg 2) Tablet containing 12.5 mg empagliflozin with 500 mg metformin hydrochloride Tablet containing 12.5 mg empagliflozin with 1 g metformin hydrochloride Tablet containing 5 mg empagliflozin with 500 mg metformin hydrochloride Tablet containing 5 mg empagliflozin with 1 g metformin hydrochloride 3) Tablet 5 mg 4) Tablet containing 2.5 mg linagliptin with 500 mg metformin hydrochloride Tablet containing 2.5 mg linagliptin with 1 g metformin hydrochloride Tablet containing 2.5 mg linagliptin with 850 mg metformin hydrochloride 1) Jardiance® 2) Jardiamet® 3) Trajenta® 4) Trajentamet® Boehringer Ingelheim Pty Limited	Type 2 diabetes mellitus (T2DM)	To request an Authority Required (STREAMLINED) for the use in triple oral therapy regimen of empagliflozin and linagliptin with metformin for the treatment of T2DM.

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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	Familial hypercholesterolaemia (FH)/ hypercholesterolaemia with symptomatic atherosclerotic cardiovascular disease (ASCVD) who do not have underlying FH	Resubmission to request an Authority Required listing for treatment of patients with FH and patients with non-familial hypercholesterolaemia who have symptomatic ASCVD.
New listing (Major Submission)	FOLLITROPIN DELTA Solution for injection 12 micrograms per 0.36 mL pre-filled cartridge Solution for injection 36 micrograms per 1.08 mL pre-filled cartridge Solution for injection 72 micrograms per 2.16 mL pre-filled cartridge Rekovelle® Ferring Pharmaceuticals Pty Ltd	Assisted reproductive technology (ART)	To request a Section 100 (IVF) Authority Required (STREAMLINED) listing for controlled ovarian stimulation in ART.
New listing (Minor Submission)	GLECAPREVIR WITH PIBRENTASVIR Tablet containing 100 mg glecaprevir with 40 mg pibrentasvir Maviret® AbbVie Pty Ltd	Chronic hepatitis C virus (HCV) infection	To request an Authority Required General Schedule and Section 100 (Highly Specialised Drug) listing for chronic HCV infection in patients who have failed prior treatment with an NS5A inhibitor.

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New listing (Minor Submission)	GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS Bars 81 g, 14 (Tylactin Complete) Tylactin Complete® Cortex Health	Tyrosinaemia	To request a Restricted Benefit Listing for the dietary management of tyrosinaemia.
New listing (Minor Submission)	GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS Sachets containing oral powder 16 g, 60 (PKU Build 10) Sachets containing oral powder 32g, 30 (PKU Build 20) PKU Build 10® PKU Build 20® Cortex Health Pty Ltd	Phenylketonuria	To request a Restricted Benefit listing for the dietary management of phenylketonuria.
Change to listing (Major Submission)	GOLIMUMAB Injection 50 mg in 0.5 mL single use pre-filled syringe Simponi® Janssen-Cilag Pty Ltd	Active non-radiographic axial spondyloarthritis	To request an Authority Required listing for the treatment of active non-radiographic axial spondyloarthritis.

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New listing (Major Submission)	GOLIMUMAB Injection 100 mg in 1 mL single use pre-filled syringe Simponi® Janssen-Cilag Pty Ltd	Moderate to severe ulcerative colitis	To request an Authority Required listing for the treatment of adult patients with moderate to severe ulcerative colitis, who have had an inadequate response to conventional therapy.
Change to recommended listing (Major Submission)	IBRUTINIB Capsule 140 mg Imbruvica® Janssen-Cilag Pty Ltd	Chronic lymphocytic leukaemia (CLL)/small lymphocytic lymphoma (SLL)	To request an Authority Required listing for the first line treatment of patients with CLL or SLL who meet certain criteria.
Change to recommended listing (Major Submission)	IBRUTINIB Capsule 140 mg Imbruvica® Janssen-Cilag Pty Ltd	Relapsed or refractory mantle cell lymphoma	Resubmission to request an Authority Required listing for the treatment of relapsed or refractory mantle cell lymphoma.
Change to listing (Minor Submission)	INFLIXIMAB Powder for I.V. infusion 100 mg Renflexis® Merck Sharp & Dohme (Australia) Pty Ltd	Multiple indications	To request that the current listings for Renflexis be changed to Authority Required (STREAMLINED) for patients continuing on treatment or switching from the reference biologic or from another bDMARD.

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New listing (Major Submission)	INSULIN DEGLUDEC WITH INSULIN ASPART Injections, cartridges, 70 units-30 units per mL, 3 mL, 5 Injections, pre-filled pen, 70 units-30 units per mL, 3 mL, 5 Ryzodeg FlexTouch® Ryzodeg Penfill® Novo Nordisk Pharmaceuticals Pty Ltd	Diabetes mellitus	To request an unrestricted listing to improve glycaemic control in adult patients with diabetes mellitus where basal and prandial insulin treatment is necessary.
New listing (Minor Submission)	INSULIN LISPRO Injections (human analogue), cartridges, 200 units per mL, 3 mL, 5 Humalog® U200 Kwikpen® Eli Lilly Australia Pty Ltd	Diabetes mellitus	To request an unrestricted listing of a new form of insulin lispro.

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Change to listing (Minor Submission)	LANREOTIDE Injection 60 mg (as acetate) in single dose pre-filled syringe Injection 90 mg (as acetate) in single dose pre-filled syringe Injection 120 mg (as acetate) in single dose pre-filled syringe Somatuline® Autogel® Ipsen Pty Ltd	Acromegaly and functional carcinoid tumour	To request that the current listing supply arrangements be changed from Section 100 (Highly Specialised Drugs Program) to Section 100 (Highly Specialised Drugs Program - Community Access).
Change to listing (Minor Submission)	LANREOTIDE Injection 120 mg (as acetate) in single dose pre-filled syringe Somatuline® Autogel® Ipsen Pty Ltd	Non-functional gastroentero-pancreatic neuroendocrine tumours (GEP-NETs)	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of non-functional GEP-NETs in adult patients with un-resectable locally advanced or metastatic disease.
Change to listing (Major Submission)	LENVATINIB Capsule 10 mg (as mesilate) Capsule 4 mg (as mesilate) Lenvima® Eisai Australia Pty Ltd	Advanced renal cell carcinoma	To request an Authority Required (STREAMLINED) listing for the treatment of patients with advanced renal cell carcinoma following treatment with at least one anti-angiogenic therapy.

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Change to listing (Minor Submission)	MEPOLIZUMAB Powder for injection 100 mg Nucala® GlaxoSmithKline Australia Pty Ltd	Uncontrolled severe eosinophilic asthma	To request an extension to the duration that eosinophil test results are considered valid to support initial access to PBS-subsidised mepolizumab.
New listing (Major Submission)	MIDOSTAURIN Capsule 25 mg Rydapt® Novartis Pharmaceuticals Australia Pty Ltd	Acute myeloid leukaemia (AML)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing of midostaurin for the treatment of patients with newly diagnosed FMS-like tyrosine kinase 3 (FLT3) mutation positive AML.
New listing (Minor Submission)	MIGALASTAT Capsule containing migalastat hydrochloride 150 mg Galafold® Amicus Therapeutics	Fabry disease	Resubmission to request a Section 100 (Highly Specialised Drug) Authority Required listing for the treatment of Fabry disease.

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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	Squamous cell carcinoma for the head and neck (SCCHN)	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of patients with squamous cell carcinoma of the head and neck (SCCHN) that progresses within 6 months following platinum-based therapy.
Change to listing (Major Submission) WITHDRAWN	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	Relapsed/refractory classical Hodgkin Lymphoma (CHL)	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of patients with relapsed/refractory CHL after autologous stem cell transplant and treatment with brentuximab vedotin.
New listing (Major Submission)	NUSINERSEN Solution for injection 12 mg in 5 mL Spinraza™ Biogen Australia Pty Ltd	Spinal muscular atrophy (SMA)	To request a Section 100 (High Specialised Drugs Program) Authority Required listing for treatment of patients with infantile-onset (Type I) and childhood-onset (Types II and III) SMA.

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Change to listing (Major Submission)	OBINUTUZUMAB Solution for I.V. infusion 1000 mg in 40 mL Gazyva® Roche Products Pty Ltd	CD20 positive follicular lymphoma	To request an Authority Required (STREAMLINED) listing for untreated patients with Stage II bulky or Stage III/IV CD20 positive follicular lymphoma.
Change to recommended listing (Major Submission)	OCRELIZUMAB Solution concentrate for I.V. infusion 300 mg in 10 mL Ocrevus® Roche Products Pty Ltd	Primary progressive multiple sclerosis (PPMS)	To request an Authority Required (STREAMLINED) listing for the treatment of adult patients with PPMS.
New listing (Major Submission)	OSIMERTINIB Tablet 40 mg Tablet 80 mg Tagrisso® AstraZeneca Pty Ltd	Locally advanced (Stage III) or metastatic (Stage IV) epidermal growth factor receptor (EGFR) T790M mutation positive non-small cell lung cancer (NSCLC)	To request an Authority Required (STREAMLINED) listing for the treatment of patients with locally advanced or metastatic EGFR T790M mutation positive NSCLC who have progressed on or after prior treatment with an EGFR tyrosine kinase inhibitor (TKI).

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New listing (Major Submission)	PALBOCICLIB Capsule 75 mg Capsule 100 mg Capsule 125 mg Ibrance® Pfizer Australia Pty Ltd	Hormone receptor-positive (HR+), human epidermal growth factor receptor-2 negative (HER2-) advanced or metastatic breast cancer	Resubmission to request an Authority Required listing as initial endocrine-based therapy in patients with HR+, HER2- locally advanced, inoperable or metastatic breast cancer in combination with a non-steroidal aromatase inhibitor.
Change to listing (Minor Submission)	PEGINTERFERON ALFA-2A Injection 135 micrograms in 0.5 mL single use pre filled syringe Injection 180 micrograms in 0.5 mL single use pre-filled syringe Pegasys® Roche Products Pty Ltd	Myeloproliferative neoplasms (MPN)	To request the current Section 100 (Highly Specialised Drugs) Authority Required (STREAMLINED) listing to be changed to an unrestricted listing.
Change to listing (Major Submission)	PEMBROLIZUMAB Powder for injection 50 mg Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® Merck Sharp & Dohme (Australia) Pty Ltd	Locally advanced or metastatic urothelial cancer (LA or mUC)	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of LA or mUC after the failure of a prior platinum-containing regimen.

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Change to listing (Major Submission)	PEMBROLIZUMAB Powder for injection 50 mg Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® Merck Sharp & Dohme (Australia) Pty Ltd	First-line treatment of patients with metastatic non-small cell lung cancer (NSCLC)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing as first line monotherapy in patients expressing PD-L1 for NSCLC.
Change to listing (Minor Submission)	POMALIDOMIDE Capsule 3 mg Capsule 4 mg Pomalyst® Celgene Pty Ltd	Relapsed/refractory multiple myeloma	Resubmission to request an amendment to the S100 (Highly Specialised Drug) listing to include patients with relapsed or refractory multiple myeloma who are contraindicated or intolerant to bortezomib and/or lenalidomide.
Change to listing (Minor Submission)	PONATINIB Tablet 15 mg (as hydrochloride) Tablet 45 mg (as hydrochloride) Inclusig® Specialised Therapeutics Australia	Relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukaemia (ALL)	To request a change to the current Authority Required listing for the treatment of Philadelphia chromosome positive ALL to remove the requirement to have a T315I mutation.

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New listing (Minor Submission)	PRALATREXATE Solution for I.V. infusion 20 mg in 1 mL Folotyn® Mundipharma Pty Ltd	Peripheral T-Cell Lymphoma	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of patients with peripheral T-cell lymphoma who are refractory to, or have relapsed following, first line chemotherapy.
New listing (Minor Submission)	RADIUM (223Ra) Injection containing radium (223Ra) dichloride 6.6 MBq in 6 mL vial Xofigo® Bayer Australia Ltd	Metastatic castrate resistant prostate cancer (mCRPC)	To request the Authority Required listing for the treatment of mCRPC.
New listing (Major Submission)	RIBOCICLIB Tablet 200 mg Kisqali® Novartis Pharmaceuticals Australia Pty Ltd	Hormone receptor-positive (HR+), human epidermal growth factor receptor-2 negative (HER2-) advanced or metastatic breast cancer	Resubmission to request an Authority Required listing as initial endocrine-based therapy in patients with HR+, HER2- locally advanced, inoperable or metastatic breast cancer in combination with a non-steroidal aromatase inhibitor, who are not premenopausal.
New listing (Minor Submission)	SEVELAMER Powder for oral liquid 2.4 g (as carbonate) Renvela® Sanofi-Aventis Australia Pty Ltd	Hyperphosphataemia in patients with chronic kidney disease	To request an Authority Required (STREAMLINED) listing of new form of sevelamer.

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New listing (Major Submission)	SODIUM PHENYLBUTYRATE Granules for oral suspension 483 mg (as sodium) per g, 174 g Pheburane® Orpharma Pty Ltd	Urea cycle disorder (UCD)	To request an Authority Required listing for the treatment of patients with UCD.
New listing (Major Submission)	SONEDIGIB Capsule 200 mg Odomzo® Sun Pharma ANZ Pty Ltd	Basal cell carcinoma (BCC)	To request an Authority Required listing for the treatment of patients with metastatic or locally advanced BCC who are not suitable to curative surgery or radiation therapy.
New listing (Major Submission) WITHDRAWN	STIRIPENTOL Capsule 250 mg Capsule 500 mg Sachet containing powder for oral suspension 250 mg Sachet containing powder for oral suspension 500 mg Diacomit® Emerge Health Pty Ltd	Severe myoclonic epilepsy in infancy (SMEI, also known as Dravet Syndrome)	To request an Authority Required (STREAMLINED) listing for use in combination with sodium valproate and clobazam for the treatment of patients with SMEI (also known as Dravet Syndrome) who meet certain criteria.

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New listing (Major Submission)	TEDUGLUTIDE Powder for injection 5 mg with solvent Revestive® Shire Australia Pty Ltd	Short Bowel Syndrome (SBS)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of SBS in patients who are dependent on parenteral nutrition for survival.
Change to listing (Minor Submission)	TETRACOSACTRIN Compound depot injection 1 mg in 1 mL Synacthen® Depot 1 mg/1 mL Link Medical Products Pty Ltd	Hypsarrhythmia and infantile spasms	To request the current unrestricted listing be changed to Restricted Benefit for the treatment of hypsarrythmia and/or infantile spasms.
Change to listing (Minor Submission)	TIOTROPIUM Solution for oral inhalation 2.5 micrograms (as bromide monohydrate) per actuation (60 actuations) Spiriva® Respimat® Boehringer Ingelheim Pty Ltd	Severe asthma	Resubmission to request the current Restricted Benefit listing for severe asthma be changed to Authority Required (STREAMLINED).

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New listing (Minor 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 (Australia) Pty Ltd	Metastatic colorectal cancer	Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of metastatic colorectal cancer.
Change to listing (Minor Submission)	VARENICLINE Tablet 1 mg (as tartrate) Champix® Pfizer Autralia Pty Ltd	Nicotine dependence	To request amendment on the Authority Required (STREAMLINED) listing for the treatment of nicotine dependence to enable access for patients who commence treatment in hospital.
Change to recommended listing (Minor Submission)	VENETOCLAX Tablet 10 mg Tablet 50 mg Tablet 100 mg Venclexta® AbbVie Pty Ltd	Relapsed/refractory chronic lymphoid leukaemia (CLL)	To request that the PBAC review the circumstances of listing recommended at its July 2017 meeting.

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Change to listing (Major Submission)	1. VILDAGLIPTIN 2. VILDAGLIPTIN WITH METFORMIN 1. Tablet 50 mg 2. Tablet containing 50 mg vilgagliptin with 500 mg metformin hydrochloride Tablet containing 50 mg vilgagliptin with 850 mg metformin hydrochloride Tablet containing 50 mg vilgagliptin with 1000 mg metformin hydrochloride 1. Galvus® 2. Galvumet® Novartis Pharmaceuticals Australia Pty Ltd	Type 2 diabetes mellitus (T2DM)	To request an Authority Required (STREAMLINED) listing for use in combination with insulin for the treatment of patients with T2DM.

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Sub-committee report (DUSC analysis)	DUSC Analysis – 5-aminosalicylic acid (5-ASA) utilisation Balsalazide (Colazide®, Fresenius Kabi Australia Pty Ltd) Mesalazine: (Mesasal®, Aspen Pharmaceuticals Australia Pty Ltd); (Mezavant®, Shire Australia Pty Ltd); (Pentasa®, Ferring Pharmaceuticals Pty Ltd); (Salofalk®, Orphan Australia Pty Ltd) Osalazine (Dipentum®, Clinect Pty Ltd) Sulfasalazine: (Pyralin EN®, Pfizer Australia Pty Ltd); (Salazopyrin®, Pfizer Australia Pty Ltd)	Ulcerative colitis	To report on whether the increasing utilisation of 5-aminosalicylic acid (5-ASA) medicines used to treat ulcerative colitis is due to more patients treated or higher doses. This report is in response to actions arising from the July 2017 consideration of the DUSC Ulcerative Colitis analysis.
Sub-committee report (DUSC analysis)	Everolimus (Afintor®, Novartis Pharmaceuticals Australia Pty Ltd) Sunitinib (Sutent®, Pfizer Australia Pty Ltd)	Pancreatic neuroendocrine tumours	To report on the predicted versus actual use of everolimus and sunitinib to treat well-differentiated, malignant, pancreatic neuroendocrine tumours (pNET).

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Sub-committee report (DUSC analysis)	Lenalidomide (Revlimid®, Celgene Pty Limited)	Myelodysplastic syndrome	To report on the predicted versus actual use of lenalidomide to treat myelodysplastic syndrome.
Sub-committee report (DUSC analysis)	Eculizumab (Soliris®, Alexion Pharmaceuticals Australasia Pty Ltd)	Atypical haemolytic uraemic syndrome	To report on the predicted versus actual use of eculizumab to treat atypical haemolytic uraemic syndrome (aHUS).
Sub-committee report (DUSC analysis)	Nanoparticle albumin-bound paclitaxel (Abraxane®, Specialised Therapeutics Australia Pty Ltd)	Metastatic adenocarcinoma of the pancreas	To report on the predicted versus actual use of nanoparticle albumin-bound paclitaxel to treat metastatic adenocarcinoma of the pancreas.
Sub-committee report (DUSC analysis)	Bortezomib (Velcade®, Janssen-Cilag Pty Ltd); lenalidomide (Revlimid®, Celgene Pty Ltd); pomalidomide (Pomalyst®, Celgene Pty Ltd); thalidomide (Thalomid®, Celgene Pty Ltd)	Multiple Myeloma	To report on the use of bortezomib, lenalidomide, pomalidomide and thalidomide to treat multiple myeloma; including the predicted versus actual use.

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Evaluation of Post market review	Salbutamol Terbutaline Ipratropium Beclomethasone Fluticasone Budesonide Ciclesonide Sodium cromoglycate Nedocromil sodium Montelukast Salmeterol Eformoterol Fluticasone with Salmeterol Fluticasone with Eformoterol Fluticasone with Vilanterol Budesonide with Eformoterol Oral glucocorticoids, plain (all listed brands)	Asthma	To consider the findings from the evaluation of the 2014 Post market review of PBS medicines used to treat asthma in children.