

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
NOVEMBER 2015 PBAC MEETING**

Closing date for consumer comments 7 October 2015

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 re-submissions (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)	ABATACEPT 125 mg/mL injection, 4 x 1 mL autoinjector Orencia® Bristol-Myers Squibb Australia Pty Ltd	Rheumatoid arthritis	To request an Authority Required listing for an autoinjector presentation.
Change to listing (Minor Submission)	ADALIMUMAB 40 mg/0.8 mL injection, 2 x 0.8 mL cartridges 40 mg/0.8 mL injection, 2 x 0.8 mL syringes 40 mg/0.8 mL injection, 6 x 0.8 mL cartridges 40 mg/0.8 mL injection, 6 x 0.8 mL syringes Humira® AbbVie Pty Ltd	Ulcerative colitis	Re-submission to request an Authority Required listing for the treatment of patients with moderate to severe ulcerative colitis.
Change to listing (Major Submission)	AFLIBERCEPT 40 mg/mL solution for intravitreal injection. The injection volume is 50µL (equivalent to 2mg aflibercept) / Single-use vial or pre-filled syringe / 1 single-use vial in a carton or pre-filled syringe in a blister pack. Eylea® Bayer Australia Ltd	Branch retinal vein occlusion (BRVO)	To request an Authority Required listing for the treatment of branched retinal vein occlusion.

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New listing (Minor Submission)	AMINO ACID FORMIULA with VITAMINS and MINERALS without LYSINE and LOW IN TRYPTOPHAN oral liquid: powder for, 30 x 18 g sachets GA1 Anamix Junior® Nutricia Australia Pty Ltd	Medicinal food	To request a Restricted Benefit listing for glutaric aciduria type 1.
New listing (Minor Submission)	AMINO ACID FORMULA with VITAMINS and MINERALS without METHIONINE oral liquid: powder for, 30 x 36 g sachets HCU Anamix Junior® Nutricia Australia Pty Ltd	Medicinal food	To request a Restricted Benefit listing for pyridoxine non-responsive homocystinuria.
New listing (Minor Submission)	AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE oral liquid, 30 x 130 mL cans PKU Easy Liquid® Orpharma Pty Ltd	Medicinal food	To request a Restricted Benefit listing for phenylketonuria.

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New listing (Minor Submission)	AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE oral liquid: powder for, 30 x 34 g bottles PKU Easy Shake & Go® Orpharma Pty Ltd	Medicinal food	To request a Restricted Benefit listing for phenylketonuria.
New listing (Minor Submission)	AMINO ACID FORMULA with VITAMINS and MINERALS without PHENYLALANINE oral liquid: powder for, 30 x 20 g sachets PKU Go® Orpharma Pty Ltd	Medicinal food	To request a Restricted Benefit listing for phenylketonuria.
New listing (Minor Submission)	AMINO ACID FORMULA with VITAMINS, MINERALS and LONG CHAIN POLYUNSATURATED FATTY ACIDS without PHENYLALANINE oral liquid, 20 x 500 mL PKU Baby® Orpharma Pty Ltd	Medicinal food	To request a Restricted Benefit listing for phenylketonuria.

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New listing (Minor Submission)	AMINO ACID FORMULA without PHENYLALANINE tablets, 110 g x 4 bottle PKU Easy Microtabs® Orpharma Pty Ltd	Medicinal food	To request a Restricted Benefit listing for phenylketonuria.
New listing (Minor Submission)	AMINO ACID FORMULA wth VITAMINS and MINERALS without METHIONINE, THREONINE and VALINE and LOW IN ISOLEUCINE oral liquid: powder for, 30 x 18 g sachets MMA/PA Anamix Junior® Nutricia Australia Pty Ltd	Medicinal food	To request a Restricted Benefit listing for methylmalonic acidaemia and propionic acidaemia.
Change to listing (Minor Submission)	AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED with LONG CHAIN POLYUNSATURATED FATTY ACIDS and MEDIUM CHAIN TRIGLYCERIDES oral liquid: powder for, 400 g Alfamino® Alfaminor Junior® Nestlé Health Science (Nestlé Australia Ltd)	Medicinal food	To request an Authority Required listing for patients with eosinophilic oesophagitis and patients with severe intestinal malabsorption.

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New listing (Major Submission)	APREMILAST 10 mg tablet [4] & 20 mg tablet [4] & 30 mg tablet [19], 1 pack 30 mg tablet, 56 Otezla® Celgene Pty Ltd	Psoriatic arthritis	Re-submission to request an Authority Required listing for the treatment of severe active psoriatic arthritis.
Change to listing (Major Submission)	APREPITANT 165 mg capsule Emend® Merck Sharp & Dohme (Australia) Pty Limited	Chemotherapy induced nausea and vomiting	To request an extension to the current Section 100 and Section 85 PBS listing to include use with carboplatin/oxaliplatin regimens from the first chemotherapy cycle without having a prior episode of chemotherapy induced nausea and vomiting.
New listing (Major Submission)	ARMODAFINIL 50 mg tablet, 30 150 mg tablet, 30 250 mg tablet, 30 Nuvigil® Teva Pharma Australia Pty Ltd	Narcolepsy	To request an Authority Required listing for the treatment of narcolepsy.

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Change to listing (Major Submission)	ARSENIC 10 mg/10 mL injection, 10 x 10 mL vials Phenasen® Phebra	Acute promyelocytic leukaemia	To request an extension to the current Section 100 PBS listing of arsenic trioxide injection to include first-line treatment of acute promyelocytic leukaemia (APL).
New listing (Major Submission)	ATAZANAVIR + COBICISTAT atazanavir 300 mg + cobicistat 150 mg tablet, 30 Evotaz® Bristol-Myers Squibb Australia Pty Ltd	HIV infection	To request Section 100 HSD Authority Required (STREAMLINED) listing for the treatment of HIV-1 infection.
Change to listing (Major Submission)	BEVACIZUMAB 100 mg and 400 mg single dose vials containing 4 mL and 16 mL, respectively, of bevacizumab (25 mg/mL) Avastin® Roche Products Pty Ltd	Advanced cervical cancer	To request Section 100 Authority Required (STREAMLINED) listing for the treatment of patients with persistent, recurrent or metastatic cervical cancer not amenable to curative treatment with surgery and/or radiation, in combination with platinum-based chemotherapy or topotecan plus paclitaxel.

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New listing (Major Submission)	BLINATUMOMAB 38.5 microgram injection [1 vial] (&) inert substance solution [10 mL vial], 1 pack Blincyto® Amgen	Philadelphia chromosome-negative relapsed or refractory B-precursor acute lymphoblastic leukaemia	To request Section 100 HSD Authority Required for the treatment of relapsed or refractory acute lymphoblastic leukaemia in both in-patient and outpatient setting.
Change to listing (Minor Submission)	BUPRENORPHINE 5 microgram/hour patch, 2 10 microgram/hour patch, 2 20 microgram/hour patch, 2 Norspan® Mundipharma Pty Ltd	Chronic pain	To request a Streamlined Authority listing for patients requiring ongoing therapy.
Change to listing (Major Submission)	CALCIPOTRIOL + BETAMETHASONE calcipotriol 0.005% + betamethasone (as dipropionate) 0.05% gel, 30 g & 60 g Daivobet® LEO Pharma Pty Ltd	Chronic stable plaque psoriasis	To request amendments to the current PBS listing of calcipotriol + betamethasone gel for the treatment of chronic stable psoriasis vulgaris of the scalp to include treatment of the body and amend the current PBS listing of the 60 g presentation from Authority Required listing to Restricted benefit.

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Change to listing (Minor Submission)	CEFUROXIME cefuroxime axetil powder for oral Suspension 125 mg (base) per 5 mL, 100 mL cefuroxime 250 mg tablets, 20 Zinnat® Aspen Pharmacare Australia Pty Ltd	Bacterial infection	To request Unrestricted benefit for two new pack sizes, 125 mg/5 mL in 100 mL oral suspension and 250 mg tablets in a pack size of 20.
New listing (Minor Submission)	CITRULLINE 1 g tablet, 300 Citrulline Easy Tablets® Orpharma Pty Ltd	Medicinal food	To request a Restricted Benefit listing for urea cycle disorders.
Change to listing (Minor Submission)	DABRAFENIB and TRAMETINIB dabrafenib 50 mg capsule, 120 dabrafenib 75 mg capsule, 120 trametinib 2 mg tablet, 30 trametinib 500 microgram tablet, 30 Tafinlar® Mekinist® Novartis Oncology	Melanoma	To request a change from an Authority Required listing to an Authority Required (STREAMLINED) listing.

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Change to recommended listing (Major Submission)	DACLATASVIR 30 mg tablet, 28 60 mg tablet, 28 Daklinza® Bristol-Myers Squibb Australia Pty Ltd	Combination with sofosbuvir for chronic hepatitis C	Re-submission for Authority Required (STREAMLINED) listing for the treatment of chronic hepatitis C virus infection and to provide an update of the clinical trial and early access programme data.
New listing (Major Submission)	DARUNAVIR + COBICISTAT darunavir 800 mg + cobicistat 150 mg tablet, 30 Prezcobix® Janssen Cilag Pty Ltd	HIV infection	To request Section 100 HSD Authority Required (STREAMLINED) listing for the treatment of HIV infection in treatment experienced patients and in patients with no darunavir resistance associated mutations.
New listing (Major Submission)	ELVITEGRAVIR, COBICISTAT, EMTRICITABINE and TENOFOVIR ALAFENAMIDE tenofovir alafenamide 10 mg + emtricitabine 200 mg + elvitegravir 150 mg + cobicistat 150 mg tablet, 30 TBC Gilead Sciences Pty Ltd	HIV infection	To request Section 100 HSD Authority Required (STREAMLINED) for the treatment of HIV infection

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Change to listing (Major Submission)	<p>EMPAGLIFLOZIN</p> <p>10 mg tablet, 30 25 mg tablet, 30</p> <p>Jardiance®</p> <p>Boehringer Ingelheim</p>	Type 2 diabetes	To request an Authority Required (STERAMLINED) listing of empagliflozin as add-on to insulin for the treatment of patients with type 2 diabetes.
New listing (Major Submission)	<p>EMPAGLIFLOZIN with METFORMIN</p> <p>empagliflozin 5 mg + metformin hydrochloride 500 mg tablet, 60 empagliflozin 5 mg + metformin hydrochloride 850 mg tablet, 60 empagliflozin 5 mg + metformin hydrochloride 1 g tablet, 60 empagliflozin 12.5 mg + metformin hydrochloride 500 mg tablet, 60 empagliflozin 12.5 mg + metformin hydrochloride 850 mg tablet, 60 empagliflozin 12.5 mg + metformin hydrochloride 1 g tablet, 60</p> <p>TBC</p> <p>Boehringer Ingelheim</p>	Type 2 diabetes	To request an Authority Required (STREAMLINED) listing of empagliflozin with metformin fixed dose combination (FDC) for the treatment of patients with type 2 diabetes.

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Change to listing (Major Submission)	EMPAGLIFLOZIN oral tablet, 10 mg, 30 oral tablet, 25 mg, 30 Jardiance® Boehringer Ingelheim Pty Ltd	Type 2 diabetes (triple therapy)	To request an Authority Required (STREAMLINED) listing of empagliflozin for use in combination with metformin and a sulfonylurea (triple therapy) for the treatment of patients with type 2 diabetes.
Change to listing (Major Submission)	ENZALUTAMIDE 40 mg capsule, 112 Xtandi® Astellas Pharma Australia Pty Ltd	Metastatic castration resistant prostate cancer	To request an Authority Required listing for the treatment of metastatic castration-resistant prostate cancer in chemotherapy-naïve patients.
Change to listing (Minor Submission)	EVEROLIMUS 250 microgram tablet, 60 500 microgram tablet, 60 750 microgram tablet, 60 1 mg tablet, 60 Certican® Novartis Pharmaceuticals Australia Pty Ltd	Prophylaxis of organ rejection	To request a change from an Authority Required listing to an Unrestricted listing for transplant indications under the General Schedule.

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New listing (Minor Submission)	FENTANYL CITRATE (BUCCAL) 100 microgram tablet: buccal, 4 100 microgram tablet: buccal, 28 200 microgram tablet: buccal, 4 200 microgram tablet: buccal, 28 400 microgram tablet: buccal, 4 400 microgram tablet: buccal, 28 600 microgram tablet: buccal, 4 600 microgram tablet: buccal, 28 800 microgram tablet: buccal, 4 800 microgram tablet: buccal, 28 Fentora® Teva Pharma Australia Pty Ltd	Breakthrough pain	Re-submission to request an Authority Required (Palliative Care Schedule) listing for the treatment of breakthrough cancer pain.
New listing (Major Submission)	FLUTICASONE FUROATE 100 microgram/actuation inhalation: powder for, 30 actuations 200 microgram/actuation inhalation: powder for, 30 actuations Arnuity® Ellipta® GlaxoSmithKline Australia Pty Ltd	Asthma	To request Unrestricted listing for the treatment of asthma.

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New listing (Minor Submission)	GLUCOSE INDICATOR BLOOD Diagnostic, 100 diagnostic strips 2in1 Smart Blood Glucose measuring test strips Merchantshub Networks (AustPacific) Pty Ltd	Diabetes	To request an Unrestricted benefit listing and Restricted benefit listing for blood glucose monitoring.
Change to listing (Minor Submission)	GLYCOMACROPEPTIDE and ESSENTIAL AMINO ACIDS with VITAMINS and MINERALS oral liquid: powder for, 30 x 49 g sachets Camino Pro Bettermilk® Cortex Health Pty Ltd	Medicinal food	To request an increase in pack size, from 28 sachets to 30 sachets per pack.
Change to listing (Minor Submission)	HIGH FAT FORMULA with VITAMINS, MINERALS and TRACE ELEMENTS and LOW IN PROTEIN and CARBOHYDRATE (4:1 ratio long chain fat to carbohydrate plus protein) oral liquid: powder for, 300 g KetoCal® Nutricia Australia Pty Ltd	Medicinal food	To advise the PBAC and Nutritional Products Working Party of an upgrade to the formulation.

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Change to listing (Major Submission)	HPV types 16 and 18 injection, 0.5 mL syringe Cervarix® GlaxoSmithKline Australia Pty Ltd	Human papillomavirus	To request inclusion in the National Immunisation Program for the prevention of persistent infection, premalignant cervical lesions and cervical cancer caused by human papillomavirus types 16 and 18.
New listing (Minor Submission)	IBRUTINIB 140 mg capsules, 90 Imbruvica® Janssen Cilag Pty Ltd	Chronic lymphocytic leukaemia and small lymphocytic lymphoma	Re-submission to request Authority Required (STREAMLINED) listing for the treatment of relapsed or refractory chronic lymphocytic leukaemia and relapsed or refractory small lymphocytic lymphoma.
New listing (Major Submission)	IDELALISIB 100 mg tablet, 60 150 mg tablet, 60 Zydelig® Gilead Sciences Pty Ltd	Chronic lymphocytic leukaemia	Re-submission to request Authority Required (STREAMLINED) listing for the treatment chronic lymphocytic leukaemia in patients with progressive disease despite previous treatment.
New listing (Major Submission)	IDELALISIB 100 mg tablet, 60 150 mg tablet, 60 Zydelig® Gilead Sciences Pty Ltd	Follicular lymphoma	Re-submission to request Authority Required (STREAMLINED) listing for the treatment of relapsed/refractory follicular lymphoma that has progressed despite prior treatment with rituximab and an alkylating agent

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New listing (Minor Submission)	INSULIN GLARGINE 100 international units/mL injection, 5 x 3 mL cartridges Basaglar®, Basaglar KwikPen® Eli Lilly Australia Pty Ltd	Diabetes	To request further advice from the PBAC regarding its previous recommendation for the PBS listing of Basaglar.
New listing (Minor Submission)	ITRACONAZOLE 50 mg capsule, 60 Lozanoc® Mayne Pharma International Pty Ltd	Systemic fungal infections	Re-submission to request an Authority Required (STREAMLINED) listing for the treatment of systemic mycoses.
Matters Outstanding (Minor Submission)	IVACAFTOR 150 mg tablet, 56 Kalydeco® Vertex Pharmaceuticals (Australia) Pty Ltd	Cystic fibrosis	To present additional efficacy and safety data in patients aged 6 years and older who have a G551D or other gating (class III) mutation in the CFTR gene who have severe cystic fibrosis.

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Change to listing (Major Submission)	LANREOTIDE ACETATE 60 mg injection, 1 syringe 90 mg injection, 1 syringe 120 mg injection ,1 syringe Somatulin Autogel® Ipsen Pty Ltd	Gastroenteropancreatic neuroendocrine tumours	To request an Authority Required (STREAMLINED) listing for the treatment for patients with gastroenteropancreatic neuroendocrine tumours with unresectable locally advanced or metastatic disease.
Change to listing (Major Submission)	LENALIDOMIDE 5 mg capsule 10 mg capsule 15 mg capsule 25 mg capsule Revlimid® Celgene Pty Ltd	Multiple myeloma	To request extension to Section 100 HSD Authority Required listing of lenalidomide to include use in the treatment of patients with symptomatic multiple myeloma who are ineligible for stem cell transplant.
New listing (Major Submission)	LENVATINIB 4 mg capsule, 30 10 mg capsule, 30 Lenvima® Eisai Australia Pty Ltd	Differentiated thyroid cancer	To request an Authority Required listing for the treatment of radioactive iodine refractory differentiated thyroid cancer (RR-DTC)

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Change to listing (Minor Submission)	MESALAZINE 1.2 g tablet: modified release, 60 Mezavant® Shire Australia Pty Ltd	Ulcerative colitis	To request an increase in the maximum PBS listed quantity, from 60 tablets to 120 tablets.
Other business (Minor Submission)	NAB-PACLITAXEL paclitaxel nanoparticle albumin bound 100 mg injection, vial Abraxane® Specialised Therapeutics Australia	Breast cancer	To request that the PBAC reconsider the exclusion of nab-paclitaxel from use in combination with PBS-subsidised trastuzumab for the treatment of HER2 positive metastatic breast cancer.
New listing (Major Submission)	NALMEFENE 18 mg tablet, 28 Selincro® Lundbeck Australia Pty Ltd	Alcohol dependence	To request Authority required listing for the treatment of patients with alcohol dependence.

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New listing (Minor Submission)	NETUPITANT and PALONOSETRON netupitant 300 mg + palonosetron 500 microgram capsule, 1 Akynzeo® Specialised Therapeutics Australia	Nausea and vomiting	Re-submission to request Authority Required (STREAMLINED) and Section 100 (Efficient Funding of Chemotherapy - Related Benefits) listing for the prevention of nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy.
New listing (Major Submission)	NINTEDANIB 100 mg capsule, 60 150 mg capsule, 60 Ofev® Boehringer Ingelheim Pty Ltd	Idiopathic pulmonary fibrosis	Re-submission to request an Authority Required listing for the treatment of idiopathic pulmonary fibrosis.
New listing (Major Submission)	NIVOLUMAB and IPILIMUMAB nivolumab 40 mg/4 mL concentrate solution for infusion, 4 mL vial nivolumab 100 mg/10 mL concentrate solution for infusion, 10 mL vial ipilimumab 200 mg/40 mL concentrate solution for infusion, 40 mL vial ipilimumab 50 mg/10 mL concentrate solution for infusion, 10 mL vial Opdivo® + Yervoy® Bristol-Myers Squibb Australia Pty Ltd	Melanoma	To request Section 100 Authority Required (STREAMLINED) listing for the treatment of patients with unresectable metastatic melanoma.

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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 (Minor Submission)	NIVOLUMAB 40 mg/4 mL concentrate solution for infusion, 4 mL vial 100 mg/10 mL concentrate solution for infusion, 10 mL vial Opdivo® Bristol-Myers Squibb Australia Pty Ltd	Melanoma	Re-submission to request Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of patients with unresectable stage III or stage IV malignant melanoma.
Change to listing (Major Submission)	OMALIZUMAB 150 mg/mL injection, 1 x 1 mL syringe Xolair® Novartis Pharmaceuticals Australia Pty Ltd	Severe chronic idiopathic urticaria	To request Section 100 Authority Required PBS listing for the treatment of patients with severe uncontrolled chronic idiopathic urticaria.
Change to listing (Minor Submission)	OMALIZUMAB 75 mg/0.5 mL injection, 1 x 0.5 mL syringe 150 mg/mL injection, 1 x 1 mL syringe Xolair® Novartis Pharmaceuticals Australia Pty Ltd	Severe allergic asthma	To propose a revision of PBS restrictions for omalizumab for the treatment of severe allergic asthma.

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New listing (Major Submission)	PASIREOTIDE 20 mg IM injection 40 mg IM injection 60 mg IM injection Signifor® Novartis Pharmaceuticals Australia Pty Ltd	Inadequately controlled acromegaly	To request Section 100 HSD Authority Required listing for the treatment of acromegaly in patients failing therapy on existing somatostatin analogues
New listing (Major Submission)	PIRFENIDONE 267 mg capsule, 270 Esbriet® Roche Products Pty Ltd	Idiopathic pulmonary fibrosis	To request Section 100 HSD Authority Required listing for the treatment of patients with idiopathic pulmonary fibrosis
New listing (Major Submission)	PRALATREXATE 20 mg/mL injection, 1 mL vial Folotyn® Mundipharma Pty Ltd	peripheral T-cell lymphoma	To request Section 100 Authority Required listing for the treatment of patients with peripheral T-cell lymphoma.

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Change to listing (Minor Submission)	PROPRANOLOL 3.75 mg/mL oral liquid, 2 x 120 mL Hemangirol® Pierre Fabre Australia Pty Ltd	Infantile hemangioma	Re-submission for an Authority Required listing for the treatment of proliferating infantile hemangioma requiring systemic therapy.
New listing (Major Submission)	PROTEIN FORMULA WITH CARBOHYDRATE, FAT, FIBRE, VITAMINS AND MINERALS oral liquid, 8 x 500 mL pouches Nutrini Low Energy Multi Fibre Nutricia Australia Pty Ltd	Dietary management of disease related malnutrition	To request a Restricted benefit listing for the dietary management of disease related malnutrition in children with low energy tube feeding requirements.
Change to listing (Minor Submission)	RISPERIDONE various forms and strengths Risperdal® Janssen Cilag Pty Ltd	Behavioural disturbances in patients with dementia	To request a change in the PBS restriction to specify moderate to severe dementia of the Alzheimer type and with a limited duration of 12 weeks treatment, to align with the safety related updated TGA indication.

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Change to listing (Minor Submission) WITHDRAWN	SAXAGLIPTIN SAXAGLIPTIN and METFORMIN XR saxagliptin 2.5 mg saxagliptin 5 mg saxagliptin 5 mg + metformin hydrochloride 500 mg tablet: modified release, 28 saxagliptin 5 mg + metformin hydrochloride 1000 mg tablet: modified release, 28 saxagliptin 2.5 mg + metformin hydrochloride 1000 mg tablet: modified release, 56 Onglyza® Kombiglyze XR® Astra Zeneca Pty Ltd	Type 2 diabetes mellitus	Re-submission to request extension of the current Authority Required (STREAMLINED) listing for use in combination with insulin in patients with type 2 diabetes.

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<p>Change to listing (Minor Submission)</p>	<p>SITAGLIPTIN SITAGLIPTIN and METFORMIN SITAGLIPTIN and METFORMIN XR</p> <p>sitagliptin 100 mg tablet, 28 sitagliptin 50 mg tablet, 28 sitagliptin 25 mg tablet, 28</p> <p>sitagliptin 50 mg + metformin hydrochloride 1000 mg tablet, 56 sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56 sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56</p> <p>sitagliptin 100 mg + metformin hydrochloride 1000 mg tablet: modified release, 28 sitagliptin 50 mg + metformin hydrochloride 1000 mg tablet: modified release, 56</p> <p>Januvia® Janumet® Janumet XR®</p> <p>Merck Sharp & Dohme (Australia) Pty Limited</p>	<p>Type 2 diabetes mellitus</p>	<p>Re-submission to request extension of the current Authority Required (STREAMLINED) listing for use in combination with insulin in patients with type 2 diabetes.</p>
<p>Change to listing (Major Submission)</p>	<p>SORAFENIB</p> <p>200 mg tablet, 120</p> <p>Nexavar®</p> <p>Bayer Australia Ltd</p>	<p>Differentiated thyroid cancer</p>	<p>Re-submission to request an Authority Required (STREAMLINED) listing for the treatment of locally advanced or metastatic, radioactive iodine refractory differentiated thyroid cancer (RAI-R DTC).</p>

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New listing (Minor Submission)	<p>THYROXINE SODIUM</p> <p>25 microgram tablet, 200 50 microgram tablet, 200 75 microgram tablet, 200 100 microgram tablet, 200 125 microgram tablet, 200 200 microgram tablet, 200</p> <p>Eltroxin®</p> <p>Aspen Pharmacare Australia Pty Ltd</p>	Thyroid hormone deficiency	To request Unrestricted benefit listing of a new brand and additional strengths of thyroxine sodium.
New listing (Minor Submission)	<p>TRIGLYCERIDES MEDIUM CHAIN</p> <p>oral liquid, 12 x 500 mL pouches</p> <p>Peptamen Junior Liquid Peptamen Junior Advance</p> <p>Nestlé Health Science (Nestlé Australia Ltd)</p>	Medicinal food	To request a Restricted Benefit listing for dietary management of conditions requiring a source of medium chain triglycerides limited to fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders.
Change to listing (Minor Submission)	<p>TRIGLYCERIDES MEDIUM CHAIN</p> <p>oral liquid: powder for, 400 g</p> <p>Monogen®</p> <p>Nutricia Australia Pty Ltd</p>	Medicinal food	To advise the PBAC and Nutritional Products Working Party of an upgrade to the formulation.

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New listing (Major Submission)	VINFLUNINE DITARTRATE 50 mg/2 mL injection: concentrated, 2 mL vial 250 mg/10 mL injection: concentrated, 10 mL vial Javlor® Pierre Fabre Pty Ltd.	Advanced or metastatic transitional cell carcinoma of the urothelial tract	Re-submission to request an Authority Required listing for the treatment of advanced or metastatic transitional cell carcinoma of the urothelial tract after failure of a prior platinum-containing regimen.
Sub-committee report (DUSC Analysis)	Pregabalin (Lyrica®)	Neuropathic pain	To examine the utilisation of pregabalin for neuropathic pain in the 24 months after PBS listing
Sub-committee report (DUSC Analysis)	Ipilimumab (Yervoy®) and dabrafenib (Tafinlar®)	Unresectable melanoma	To review the predicted versus actual use of ipilimumab and dabrafenib for unresectable melanoma
Sub-committee report (DUSC Analysis)	Fingolimod (Gilenya®), dimethyl fumarate (Tecfidera®), teriflunomide (Aubagio®), interferon beta-1a (Avonex®, Rebif®), interferon beta-1b (Betaferon®), glatiramer acetate (Copaxone®)	Multiple sclerosis	To review the utilisation of PBS listed medicines for relapsing-remitting multiple sclerosis (RRMS), including an assessment of the predicted versus actual use of the oral therapies, dimethyl fumarate, teriflunomide and fingolimod

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Sub-committee report (DUSC Analysis)	Over 150 nutritional products listed on the PBS Schedule	Nutritional Products	To assess the utilisation of food and nutritional products listed on the Pharmaceutical Benefits Scheme (PBS)
Sub-committee report (DUSC Analysis)	Adalimumab (Humira®), etanercept (Enbrel®), infliximab (Remicade®), golimumab (Simponi®), certolizumab pegol (Cimzia®)	Psoriatic arthritis	To examine the PBS use of biological disease modifying anti-rheumatic drugs (bDMARDs) used to treat psoriatic arthritis
Sub-committee report (DUSC Analysis)	Alprazolam (all current and previously listed brands including generic versions)	Panic disorder	To assess the PBS utilisation of alprazolam in the 12 months following its rescheduling from Schedule 4 (S4) to Schedule 8 (S8) in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)