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| 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. |

| **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.) |
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| New listing  (Major Submission) | ACALABRUTINIB  Capsule 100 mg  Calquence®  AstraZeneca Pty Ltd | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) | To request an Authority Required listing for the treatment of patients with relapsed or refractory CLL or SLL considered unsuitable for treatment with a purine analogue. |
| New listing  (Minor Submission) | ADALIMUMAB  Injection 40 mg in 0.8 mL pre-filled syringe, 2 Injection 40 mg in 0.8 mL pre-filled pen, 2 Injection 40 mg in 0.8 mL pre-filled syringe, 6 Injection 40 mg in 0.8 mL pre-filled pen, 6  Hyrimoz®  Sandoz Pty Ltd | Crohn disease Ulcerative colitis Juvenile idiopathic arthritis Fistulising Crohn disease Rheumatoid arthritis Psoriatic arthritis Ankylosing spondylitis Chronic plaque psoriasis Hidradenitis suppurativa | To request an Authority Required listing of a biosimilar adalimumab under the same conditions as the reference biologic. |
| Change to recommended listing   (Minor Submission) | ALIROCUMAB  Injection 75 mg in 1 mL single dose pre-filled pen Injection 150 mg in 1 mL single dose pre-filled pen  Praluent®  Sanofi-aventis Australia Pty Ltd | Hypercholesterolaemia | Resubmission to request an Authority Required listing for the treatment of hypercholesterolaemia in patients with atherosclerotic cardiovascular disease and additional high-risk factors. |
| Change to listing  (Minor Submission) | AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE  Sachets containing oral powder 27.8 g, 30   PKU Lophlex®  Nutricia Australia Pty Ltd | Phenylketonuria (PKU) | To request a formulation change to PKU Lophex® for the dietary management of patients with PKU. |
| Change to listing  (Minor Submission) | AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS  Oral powder 400 g  Neocate LCP®  AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS  Oral powder 400 g  Neocate Syneo®  Nutricia Australia Pty Ltd | Cow’s milk allergy, multiple food intolerance and other medical conditions where an amino acid-based formula is recommended | To request a formulation change to Neocate LCP® and Neocate Syneo® for the dietary management of patients with Cow’s milk allergy, multiple food intolerance and other medical conditions where an amino acid-based formula is recommended. |
| Change to listing  (Minor Submission) | APOMORPHINE  Injection containing apomorphine hydrochloride hemihydrate 100 mg in 20 mL, Solution for subcutaneous injection containing apomorphine hydrochloride 30 mg in 3 mL pre-filled pen  Apomine solution for infusion®;  Apomine Intermittent®  Pfizer Australia Pty Ltd | Parkinson disease | To request General Schedule, Authority Required (STREAMLINED) listings of apomorphine for the continuing treatment of Parkinson Disease for patients who meet certain conditions, following initiation with the current Section 100 (Highly Specialised Drugs Program) listings. |
| Change to listing  (Major Submission) | ATEZOLIZUMAB  Solution concentrate for I.V. infusion 840 mg in 14 mL  Tecentriq®  Roche Products Pty Ltd | Breast cancer | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the first-line treatment of patients with unresectable locally advanced or metastatic triple-negative breast cancer who are programmed death-ligand 1 (PD-L1)-positive. |
| Change to recommended listing  (Minor Submission) | ATEZOLIZUMAB  Solution concentrate for I.V. infusion 840 mg in 14 mL  Tecentriq®  Roche Products Pty Ltd | Small cell lung cancer (SCLC) | To request listing of an additional vial size for the treatment of patients with extensive stage SCLC and to amend the recommended dosing regimens of atezolizumab for SCLC to allow clinician choice of either 1,200 mg every 3 weeks (Q3W) or 1,680 mg every 4 weeks (Q4W) dosing. |
| Change to listing  (Major Submission) | AVELUMAB  Solution concentrate for I.V. infusion 200 mg in 10 mL  Bavencio®  Merck Healthcare Pty Ltd | Renal cell carcinoma (RCC) | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED), in combination with axitinib, for the first-line treatment of patients with Stage IV clear cell variant RCC. |
| New listing  (Minor Submission) | BENRALIZUMAB  Injection 30 mg in 1 mL pre-filled pen  Fasenra Pen®  AstraZeneca Pty Ltd | Eosinophilic asthma | To request listing of an autoinjector presentation of benralizumab under the same conditions as the current pre-filled syringe. |
| 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 one or more risk factors for CDI recurrence. |
| New listing  (Minor Submission) | BROLUCIZUMAB  Solution for intravitreal injection 19.8 mg in 0.165 mL pre-filled syringe  Beovu®  Novartis Pharmaceuticals Australia Pty Limited | Subfoveal choroidal neovascularisation (CNV) | Resubmission to request an Authority Required listing for the treatment of patients with CNV due to age-related macular degeneration. |
| New listing  (Minor Submission) | BUPRENORPHINE + NALOXONE  Tablet (sublingual) containing 0.7 mg buprenorphine hydrochloride with 0.18 mg naloxone hydrochloride Tablet (sublingual) containing 1.4 mg buprenorphine hydrochloride and 0.36 mg naloxone hydrochloride Tablet (sublingual) containing 2.9 mg buprenorphine hydrochloride and 0.71mg naloxone hydrochloride Tablet (sublingual) containing 5.7 mg buprenorphine hydrochloride and 1.4 mg naloxone hydrochloride Tablet (sublingual) containing 8.6 mg and 2.1mg naloxone hydrochloride Tablet (sublingual) containing 11.4 mg buprenorphine hydrochloride and 2.9 mg naloxone hydrochloride  Zubsolv®  Mundipharma Pty Ltd | Opiate dependence | Resubmission to request a Section 100 (Opiate Dependence Treatment Program) Restricted Benefit listing for the treatment of patients with opiate dependence. |
| 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). |
| New listing  (Major Submission) | DINUTUXIMAB BETA  Solution concentrate for I.V. infusion 20 mg in 4.5 mL  Qarziba®  EUSA Pharma (UK) Ltd | Neuroblastoma | To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of patients with high risk neuroblastoma or relapsed or refractory neuroblastoma. |
| 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 patients with chronic, severe, atopic dermatitis who have had an inadequate response to topical therapies. |
| New listing  (Major Submission) | ENTRECTINIB  Capsule 200 mg  Rozlytrek®  Roche Products Pty Ltd | Non-small cell lung cancer (NSCLC) | To request an Authority Required listing for the treatment of patients with locally advanced (Stage IIIB) or metastatic (Stage IV) c-ros proto-oncogene 1 (ROS1)-positive NSCLC. |
| New listing  (Major Submission) | FLUOCINOLONE ACETONIDE  Intravitreal injection 190 micrograms  Iluvien®  Specialised Therapeutics Pharma Pty Ltd | Diabetic macular oedema | To request an Authority Required listing for the treatment of patients with diabetic macular oedema who have had an inadequate response to corticosteroids. |
| Change to listing  (Minor Submission) | LISDEXAMFETAMINE  Capsule containing lisdexamfetamine dimesilate 20mg Capsule containing lisdexamfetamine dimesilate 30mg Capsule containing lisdexamfetamine dimesilate 40mg Capsule containing lisdexamfetamine dimesilate 50mg Capsule containing lisdexamfetamine dimesilate 60mg Capsule containing lisdexamfetamine dimesilate 70mg  Vyvanse®  Shire Australia Pty Limited | Attention deficit hyperactivity disorder (ADHD) | To request removal of the age of diagnosis criterion from the Authority Required listings of lisdexamfetamine for the treatment of ADHD. |
| New Listing  (Minor Submission) | MEPOLIZUMAB  Injection 100 mg in 1 mL pre-filled pen Injection 100 mg in 1 mL pre-filled syringe  Nucala®  GlaxoSmithKline Australia Pty Ltd | Eosinophilic asthma | To request listing of pre-filled syringe and pre-filled pen presentations of mepolizumab under the same conditions as mepolizumab powder for injection 100 mg. |
| Change to listing  (Minor Submission) | MESALAZINE  Suppository 1 g Sachet containing granules, 1 g per sachet  Pentasa®  Ferring Pharmaceuticals Pty Ltd | Ulcerative proctitis Ulcerative colitis  Crohn disease | To request a change to the maximum quantity for the 1 g suppository (from 30 to 28 units) and 1 g sachet containing granules (from 120 to 100 sachets) forms of the Pentasa® brand of mesalazine, in line with changes to the pack sizes. |
| New listing  (Minor Submission) | METHYLPHENIDATE  Capsule containing methylphenidate hydrochloride 60 mg (modified release)  Ritalin LA®  Novartis Pharmaceuticals Australia Pty Limited | Attention deficit hyperactivity disorder (ADHD) | To request an Authority Required listing of a new strength of modified release methylphenidate for the treatment of patients with ADHD. |
| Change to listing  (Minor Submission) | MILK PROTEIN AND FAT FORMULA WITH VITAMINS AND MINERALS CARBOHYDRATE FREE  Oral powder 225 g  Carbohydrate Free Mixture®  Nutricia Australia Pty Ltd | Ketogenic diet | To request a formulation change to Carbohydrate Free Mixture for the dietary management of patients requiring a ketogenic diet. |
| New listing  (Major Submission) | NABIXIMOLS  Oromucosal spray, 8 mg per dose, 90 doses  Sativex®  Emerge Health Pty Ltd | Multiple sclerosis (MS) related spasticity | Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of patients with moderate to severe spasticity due to MS who have had an inadequate response to other anti-spasticity medication. |
| Change to listing  (Minor Submission) | OLAPARIB  Capsule 50 mg Tablet 100 mg Tablet 150 mg   Lynparza®  AstraZeneca Pty Ltd | High grade serous ovarian cancer  High grade serous fallopian tube cancer  High grade serous primary peritoneal cancer | Resubmission to request the current Authority Required (STREAMLINED) listings for the treatment of patients with high grade serous ovarian, fallopian tube or primary peritoneal cancer be amended to include somatic BRCA 1/2 mutation testing as an option to determine eligibility for treatment. |
| New listing   (Major Submission) | OZANIMOD  Capsule 230 micrograms Capsule 460 micrograms Capsule 920 micrograms  Zeposia®  Celgene Pty Ltd | Relapsing-remitting multiple sclerosis (RRMS) | To request an Authority Required listing for the treatment of patients with RRMS. |
| New listing  (Minor Submission) | PEGFILGRASTIM  Injection 6 mg in 0.6 mL single use pre-filled syringe  Pelgraz®  Accord Healthcare Pty Ltd | Chemotherapy-induced neutropenia | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing of a biosimilar pegfilgrastim under the same conditions as the reference biologic. |
| 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 | To request an extension of the current Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of unresectable Stage III or IV malignant melanoma to allow use as a first-line therapy in patients who are BRAF V600 mutation positive. |
| Change to listing  (Major Submission) | PEMBROLIZUMAB  Solution concentrate for I.V. infusion 100 mg in 4 mL  Keytruda®  Merck, Sharp & Dohme (Australia) Pty Ltd | Primary mediastinal B-cell lymphoma (PMBCL) | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of patients with relapsed or refractory PMBCL who meet certain conditions. |
| Change to listing  (Minor Submission) | PEMBROLIZUMAB  Solution concentrate for I.V. infusion 100 mg in 4 mL  Keytruda®  Merck, Sharp & Dohme (Australia) Pty Ltd | Melanoma Non-small cell lung cancer (NSCLC) | To request amending the recommended dosing regimens of pembrolizumab for melanoma or NSCLC to allow clinician choice of either 200 mg every 3 weeks (Q3W) or 400 mg every 6 weeks (Q6W) dosing. |
| Change to listing  (Minor Submission) | PEMBROLIZUMAB  Solution concentrate for I.V. infusion 100 mg in 4 mL  Keytruda®  Merck Sharp & Dohme (Australia) Pty Ltd | Melanoma | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the adjuvant treatment of patients who have had completely surgically resected Stage IIIB-D malignant melanoma. |
| Change to listing  (Major Submission) | PERTUZUMAB  Solution for I.V. infusion 420 mg in 14 mL  Perjeta®  Roche Products Pty Limited | Breast cancer | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing, in combination with trastuzumab and chemotherapy, for the neoadjuvant treatment of patients with human epidermal growth factor receptor-2 positive (HER2+) locally advanced, inflammatory or early stage breast 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 | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing, in combination with dexamethasone, for the treatment of patients with relapsed or refractory multiple myeloma who meet certain conditions. |
| New listing  (Minor Submission) | PROTEIN FORMULA WITH CARBOHYDRATE, FAT, VITAMINS, MINERALS AND TRANSFORMING GROWTH FACTOR BETA-2  Powder for oral liquid, 400 g, 12  Modulen IBD®  Nestle Health Science | Crohn disease | To request a Restricted Benefit listing of Modulen IBD for the dietary management of Crohn disease in patients aged 5 years or older in the active or remission phase of disease. |
| New listing  (Major Submission) | RIVAROXABAN  Tablet 2.5 mg  Xarelto®  Bayer Australia | Coronary Artery Disease (CAD) and Peripheral Artery Disease (PAD) | Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients at high risk of recurrent cardiovascular events with CAD or PAD who meet certain conditions. |
| New listing  (Major Submission) | ROMOSOZUMAB  Injection 105 mg in 1.17 mL single use pre-filled syringe  Evenity®  Amgen Australia Pty Ltd | Osteoporosis | Resubmission to request an Authority Required listing for the treatment of patients with severe osteoporosis. |
| New listing  (Minor Submission) | SEMAGLUTIDE  Injection 2 mg in 1.5 mL pre-filled syringe Injection 4 mg in 3 mL pre-filled syringe  Ozempic®  Novo Nordisk Pharmaceuticals Pty Ltd | Type 2 diabetes mellitus (T2DM) | Resubmission to request the PBAC review its advice on the therapeutic relativities and equi-effective doses of semaglutide and dulaglutide as part its November 2019 recommendation for semaglutide for use in combination with metformin and/or a sulfonylurea for the treatment of patients with T2DM. |
| New listing  (Minor Submission)  Consideration suspended –  Re-categorised to major submission category under the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009*. | SIPONIMOD  Tablet 250 micrograms  Tablet 2 mg  Mayzent®  Novartis Pharmaceuticals Australia Pty Limited | Multiple sclerosis (MS) | Resubmission to request an Authority Required listing for the treatment of patients with a history of relapsing forms of MS who meet certain conditions. |
| New listing  (Major Submission) | STIRIPENTOL  Capsule 250 mg Capsule 500mg Powder for oral suspension 250 mg  Powder for oral suspension 500 mg   Diacomit®  Emerge Health Pty Ltd | Severe myoclonic epilepsy in infancy (SMEI) | To request an Authority Required (STREAMLINED) listing for adjunctive treatment of patients with generalised tonic-clonic and clonic seizures associated with SMEI (Dravet syndrome) who meet certain conditions. |
| Change to listing  (Minor Submission) | TOCILIZUMAB  Injection 162 mg in 0.9 mL single use prefilled pen Injection 162 mg in 0.9 mL single use prefilled syringe  Actemra®  Roche Products Pty Ltd | Systemic juvenile idiopathic arthritis (sJIA) | To request an extension of the current Authority Required listing of subcutaneous tocilizumab to include the treatment of patients with sJIA. |
| Change to recommended listing  (Minor Submission) | TOFACITINIB  Tablet 5 mg  Xeljanz®  Pfizer Australia Pty Ltd | Chronic plaque psoriasis Psoriatic arthritis Rheumatoid arthritis Ulcerative colitis | To request that the PBAC review its advice on the interchangeability of tofacitinib on an individual patient basis with other biological disease modifying antirheumatic drugs under Section 101(3BA) of the *National Health Act 1953*. |
| Change to listing  (Minor Submission) | TRIGLYCERIDES MEDIUM CHAIN AND LONG CHAIN WITH GLUCOSE POLYMER  Oral powder 400 g  Duocal®  Nutricia Australia Pty Ltd | Proven inborn errors of protein metabolism | To request a formulation change to Duocal for the dietary management of patients with proven inborn errors of metabolism. |
| Change to listing  (Minor Submission) | TRIGLYCERIDES MEDIUM CHAIN FORMULA  Oral powder 400 g  Lipistart®  Vitaflo Australia Pty Ltd | Dietary management of conditions requiring a source of medium chain triglycerides | To request a formulation change to Lipistart for the dietary management of patients with fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis or gastrointestinal disorders. |
| Change to listing  (Minor Submission) | TRIGLYCERIDES MEDIUM CHAIN FORMULA  Oral powder 400 g  Peptamen Junior®  Nestle Health Science | Dietary management of conditions requiring a source of medium chain triglycerides | To request an extension of the current Restricted Benefit listing to include critically or chronically ill paediatric patients who are dependent on nutritional support therapy. |
| Change to listing  (Major Submission) | VENETOCLAX  Pack containing 14 tablets venetoclax 10 mg and 7 tablets venetoclax 50 mg and 7 tablets venetoclax 100 mg and 14 tablets venetoclax 100 mg  Tablet 10 mg  Tablet 50 mg  Tablet 100 mg  Venclexta®  AbbVie Pty Ltd | Chronic lymphocytic leukaemia (CLL) | To request an Authority Required (STREAMLINED) listing, in combination with obinutuzumab, for the first-line treatment of patients with CLL who have coexisting conditions and are unsuitable for fludarabine based chemotherapy. |
| Change to listing  (Minor Submission) | WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE  Oral powder 400 g, 6 Sachets containing oral powder 100 g, 10  Renastart®  Vitaflo Australia Pty Ltd | Chronic kidney disease (CKD) | To request a formulation change to Renastart for the dietary management of eligible paediatric patients with CKD. |
| Subcommittee report  (DUSC Analysis) | Alemtuzumab  Lemtrada®  Sanofi-aventis Australia Pty Ltd | Relapsing-Remitting Multiple Sclerosis (RRMS) | To compare the predicted and actual utilisation of alemtuzumab for RRMS since it was PBS listed for this indication. |
| Subcommittee report  (DUSC Analysis) | Opioid analgesics  All brands and strengths  Various sponsors | Analgesia | To assess the utilisation of PBS listed opioid analgesics. |
| Subcommittee report  (DUSC Analysis) | Nintedanib; Pirfenidone    Ofev; Esbriet®  Boehringer Ingelheim Pty Ltd;  Roche Products Pty Ltd | Idiopathic pulmonary fibrosis (IPF) | To compare the predicted and actual utilisation of nintedanib and pirfenidone for the treatment of IPF since PBS listing. |
| Subcommittee report  (DUSC Analysis) | Testosterone Testosterone undecanoate   Various brands  Various sponsors | Treatment of androgen deficiency both with and without established pituitary or testicular disorders | To assess the impact of restriction changes that have occurred since the previous DUSC analysis in 2015. |