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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 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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| **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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| Change to listing(Minor Submission) | AFLIBERCEPT4 mg/0.1 mL injection, 1 x 0.1 mL vial, 4 mg/0.1 mL injection, 1 x 0.09 mL syringeEylea® Bayer Australia Ltd | Age related macular degeneration (AMD), central retinal vein occlusion (CRVO) and diabetic macular oedema (DME) | To request that the vial and syringe presentations be designated as equivalent for substitution purposes (i.e. 'a'-flagged). |
| New listing(Minor Submission) | AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHANoral liquid: powder for, 500 gXYLYS LOW TRY Maxamum®Nutricia Australia Pty Ltd | Medicinal food | Restricted benefit listing for patients over 8 years of age with glutaric aciduria. |
| New listing(Minor Submission) | AMINO ACID SYNTHETIC FORMULA oral liquid: powder for, 400 gAlfamino® JuniorNestle Australia Ltd | Medicinal food | To list a new formulation suitable for children aged 1 year and older for the same indications as the existing Alfamino product listed on the PBS, as well as for severe intestinal malabsorption including short bowel syndrome. |
| Change to listing(Minor Submission) | ANTI-GLAUCOMA DRUGSvariousOptometry Australia on behalf of various sponsors | Glaucoma | To amend existing arrangements so that patients treated by an optometrist can access anti-glaucoma medications through the PBS without the requirement for the prescribing optometrist to be working in shared care arrangements with an ophthalmologist. |
| Change to listing(Major Submission) | APIXABAN2.5 mg tablet, 605 mg tablet, 285 mg tablet, 60Eliquis®Bristol-Myers Squibb Australia Pty Ltd | Deep vein thrombosis or pulmonary embolism | To request Authority Required (STREAMLINED) listing for the treatment of deep vein thrombosis or pulmonary embolism. |
| New listing(Major Submission) | APREMILAST30 mg tablet, 56Starter Pack (10 mg tablet, 4; 20 mg tablet, 4; and 30 mg tablet, 19)Otezla®Celgene Pty Ltd | Moderate to severe plaque psoriasis | To request Authority Required (STREAMLINED) listing for the treatment of patients with moderate to severe plaque psoriasis. |
| New listing(Major Submission) | APREMILAST30 mg tablet, 56Starter Pack (10 mg tablet, 4; 20 mg tablet, 4; and 30 mg tablet, 19)Otezla®Celgene Pty Ltd | Severe active psoriatic arthritis | To request Authority Required (STREAMLINED) listing for the treatment of severe active psoriatic arthritis. |
| New listing(Major Submission) | ASUNAPREVIR100 mg capsule, 56Sunvepra®Bristol-Myers Squibb Australia Pty Ltd | Hepatitis C | To request Authority Required (STREAMLINED) listing for the treatment of chronic genotype 1b hepatitis C virus infection. |
| New listing(Major Submission) | BENDAMUSTINE HYDROCHLORIDE25 mg injection: powder for, 1 vial100 mg injection: powder for, 1 vialRibomustin®Janssen-Cilag Pty Ltd | Stage III and stage IV indolent non-Hodgkin's lymphoma and mantle cell lymphoma | To request Section 100 (Highly Specialised Drugs Program) listing for the treatment of stage III and stage IV indolent non-Hodgkin's lymphoma and mantle cell lymphoma. |
| Change to listing(Major Submission) | BRENTUXIMAB VEDOTIN50 mg injection: powder for, 1 vialAdcetris® Takeda Pharmaceuticals Australia Pty Ltd | Hodgkin lymphoma | To request Section 100 (Highly Specialised Drugs Program) listing for the treatment of Hodgkin lymphoma relapsed or refractory after autologous stem cell transplant. |
| New listing(Minor Submission) | BUPRENORPHINE15 microgram/hour patch, 225 microgram/hour patch, 230 microgram/hour patch, 240 microgram/hour patch, 2Norspan®Mundipharma Pty Ltd | Pain | To list additional strengths for the same indications currently applying to the existing patches.  |
| New listing(Major Submission) | CANAKINUMAB150 mg injection: powder for, 1 vial150 mg injection: powder for, 4 vialsIlaris®Novartis Pharmaceuticals Australia Pty Ltd | Systemic juvenile idiopathic arthritis | To request Authority Required listing for the treatment of systemic juvenile idiopathic arthritis. |
| New listing(Major Submission) | DACLATASVIR30 mg tablet, 2860 mg tablet, 28Daklinza® Bristol-Myers Squibb Australia Pty Ltd | Hepatitis C | To request Authority Required (STREAMLINED) listing for the treatment of chronic hepatitis C virus infection. |
| Change to listing(Major Submission) | DAPAGLIFLOZIN10 mg tablet, 28Forxiga®AstraZeneca Australia Pty Ltd |  Type 2 diabetes mellitus | To request Authority Required (STREAMLINED) listing for triple oral therapy with metformin and a sulfonylurea in patients with type 2 diabetes mellitus. |
| New listing(Major Submission) | DEXAMETHASONE700 microgram implant, 1Ozurdex®Allergan Australia Pty Ltd | Treatment of diabetic macular oedema | To request Authority Required (STREAMLINED) listing for the treatment of visual impairment due to diabetic macular oedema in patients with pseudophakia (ie, artificial lens following cataract surgery) or who are scheduled for cataract surgery. |
| New listing(Major Submission) | Diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type b conjugate vaccine (DTPa-HepB-IPV-Hib)0.5 mL pre-filled syringeHexaxim®Sanofi-Aventis Australia Pty Ltd | Diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and Haemophilus influenzae type b | To request the inclusion of DTPa-HepB-IPV-Hib on the National Immunisation Program for the primary vaccination of infants at 2, 4 and 6 months of age. |
| Change to listing(Major Submission) | ETANERCEPT50 mg injection in 1mL single use auto-injector, 4 pack50 mg injection in 1 mL single use pre-filled syringes, 4 pack25 mg injection [4 x 25 mg vials] (&) inert substance diluent [4 x 1 mL syringes], 1 packEnbrel®Pfizer Australia Pty Ltd | Nonradiographic axial spondyloarthritis | To request Authority Required listing for the treatment of nonradiographic axial spondyloarthritis. |
| New listing(Major Submission) | EVOLOCUMAB140 mg/1 mL injection, 1 x 1 mL injection device(Trade name to be confirmed)Amgen Australia Pty Ltd | Hypercholesterolaemia | To request Authority Required (STREAMLINED) listing for the treatment of hypercholesterolaemia. |
| Change to listing(Major Submission) | EXENATIDE5 microgram/0.02 mL injection: solution, 60 unit doses10 microgram/0.04 mL injection: solution, 60 unit dosesByetta®AstraZeneca Australia Pty Ltd |  Type 2 diabetes mellitus | To request Authority Required (STREAMLINED) listing for use in combination with insulin in type 2 diabetes mellitus. |
| New listing(Major Submission) | FEBUXOSTAT80 mg tablet, 28120 mg tablet, 28Adenuric®A.Menarini Australia Pty Ltd | Hyperuricaemia with deposition | To request Authority Required (STREAMLINED) listing for the treatment of chronic symptomatic hyperuricaemia with deposition (chronic gout). |
| New listing(Minor Submission) | FOLLITROPIN ALFA (RCH) + LUTROPIN ALFA (RCH) follitropin alfa (rch) 150 IU + lutropin alfa (rch) 75 IU injectionPergoveris®Merck Serono Australia Pty Ltd | Assisted reproduction | To request Section 100 (IVF/GIFT Program) Authority Required listing for patients who are receiving treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule who have severe luteinising hormone deficiency and for whom treatment with the combination product is considered to be appropriate. |
| New listing(Minor Submission) | GLATIRAMER40 mg/mL injection, 12 x 1 mL syringesCopaxone 40®bioCSL Pty Ltd | Multiple sclerosis | To request Authority Required listing of a new strength for the same indications as the existing 20 mg/mL pre-filled syringe. |
| New listing(Minor Submission) | GLUCOSE INDICATOR BLOODglucose indicator blood strip: diagnostic, 100Betachek C50®National Diagnostic Products Pty Ltd | Blood glucose monitoring | Unrestricted benefit listing (5 repeats available) and Restricted benefit listing for blood glucose monitoring (11 repeats available) |
| New listing(Minor Submission) | GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALSoral liquid, 28 x 250 mL cartonsoral liquid, 28 x 250 mL cartonsPKU Glytactin® RTD 10PKU Glytactin® RTD 15Cortex Health Pty Ltd | Medicinal food | Restricted benefit listing for phenylketonuria. |
| New listing(Major Submission) | IDELALISIB100 mg tablet, 60150 mg tablet, 60Zydelig®Gilead Sciences Pty Ltd | Chronic lymphocytic leukaemia  | To request Authority Required (STREAMLINED) listing for the treatment of chronic lymphocytic leukaemia in patients with progressive disease despite previous treatment. |
| New listing(Major Submission) | IDELALISIB100 mg tablet, 60150 mg tablet, 60Zydelig®Gilead Sciences Pty Ltd | Indolent non-Hodgkin's lymphoma | To request Authority Required (STREAMLINED) listing for the treatment of indolent subtypes of B-cell non-Hodgkin's lymphoma in patients with progressive disease despite previous treatment. |
| Change to listing(Minor Submission) | IMATINIB100 mg tablet, 56400 mg tablet, 28Glivec®Novartis Pharmaceuticals Australia Pty Ltd | Gastrointestinal stromal tumours | To amend the existing maximum quantities applying to each strength to align with the new pack sizes of 28 tablets and 56 tablets in the gastrointestinal stromal tumour listings only.  |
| New listing(Major Submission) | INFLUENZA VACCINE (quadrivalent)0.5 mL pre-filled syringeFluarix tetra®GlaxoSmithKline Australia Pty Ltd | Influenza | To request inclusion of quadrivalent influenza vaccination on the National Immunisation Program's Designated Vaccines List for the prevention of seasonal influenza. |
| New listing(Minor Submission) | INSULIN GLARGINE100 international units/mL injection, 5 x 3 mL cartridgesBasaglar®, Basaglar KwikPen®Eli Lilly Australia Pty Ltd | Diabetes | To request unrestricted benefit listing |
| Change to listing(Minor Submission) | IVABRADINE5 mg tablet, 567.5 mg tablet, 56Coralan®Servier Laboratories (Australia) Pty Ltd | Chronic heart failure | To streamline the current Authority Required listing and amend existing Prescriber Instruction to allow resting heart rate to be measured by ECG or echocardiography. |
| Change to listing(Minor Submission) | LACOSAMIDE50 mg tabletVimpat®UCB Australia Pty Ltd | Epilepsy | To allow continued treatment with the 50 mg strength tablet. |
| New listing(Major Submission) | LEDIPASVIR with SOFOSBUVIRledipasvir 90 mg + sofosbuvir 400 mg tablet, 28Harvoni®Gilead Sciences Pty Ltd | Hepatitis C | To request Section 100 (Highly Specialised Drugs Program) listing for the treatment of genotype 1 chronic hepatitis C virus infection in adult patients. |
| New listing(Major Submission) | LIGNOCAINE5% patch: dermal, 30Versatis®bioCSL Pty Ltd | Postherpetic neuralgia | To request Authority Required (STREAMLINED) listing for the treatment of patients with postherpetic neuralgia. |
| New listing(Major Submission) | LURASIDONE HYDROCHLORIDE40 mg tablet, 3080 mg tablet, 30Latuda®Commercial Eyes Pty Ltd | Schizophrenia | To request Authority Required (STREAMLINED) listing for the treatment of schizophrenia. |
| New listing(Major Submission) | LUTROPIN ALFA75 IU injection [1 x 75 IU vial] (&) inert substance diluent [1 x 1 mL vial], 1 packLuveris®Merck Serono Australia Pty Ltd | Infertility | To request Section 100 (IVF/GIFT program) listing for women who are receiving assisted reproductive medical treatment and have severe luteinising hormone deficiency. |
| New listing(Major Submission) | NETUPITANT with PALONOSETRONnetupitant 300 mg + palonosetron 500 microgram capsule, 1 Akynzeo®Specialised Therapeutics Australia Pty Ltd | Nausea and vomiting | 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 and moderately emetogenic cancer chemotherapy. |
| New listing(Major Submission) | NINTEDANIB100 mg capsule, 60150 mg capsule, 60 Ofev®Boehringer Ingelheim Pty Ltd | Non-small cell lung cancer  | To request Authority Required listing for the treatment of locally advanced, metastatic or recurrent non-small cell lung cancer. |
| New listing(Major Submission) | NINTEDANIB100 mg capsule, 60150 mg capsule, 60 Ofev®Boehringer Ingelheim Pty Ltd | Idiopathic pulmonary fibrosis | To request Authority Required listing for the treatment of idiopathic pulmonary fibrosis for patients aged 40 years or older. |
| New listing(Major Submission) | OBINUTUZUMAB1 g/40 mL injection, 40 mL vialGazyva®Roche Products Pty Ltd | Chronic lymphocytic leukaemia | To request Section 100 (Efficient Funding of Chemotherapy) listing for the treatment of chronic lymphocytic leukaemia. |
| New listing(Minor Submission) | OXYCODONE + NALOXONEoxycodone hydrochloride 2.5 mg + naloxone hydrochloride 1.25 mg tablet: modified release, 28 tabletsoxycodone hydrochloride 15 mg + naloxone hydrochloride 7.5 mg tablet: modified release, 28 tabletsoxycodone hydrochloride 30 mg + naloxone hydrochloride 15 mg tablet: modified release, 28 tabletsTargin®Mundipharma Pty Ltd | Pain | To list additional strengths for the same indications currently applying to the existing tablets. |
| New listing(Minor Submission) | OXYCODONE5 mg tablet: modified release, 28Oxycodone Sandoz® 5 mg Sandoz Pty Ltd | Pain | To request Restricted benefit listing for chronic severe disabling pain not responding to non-narcotic analgesics. |
| Change to listing(Minor Submission) | PANITUMUMAB100 mg/5 mL injection, 1 x 5 mL vial400 mg/20 mL injection, 1 x 20 mL vialVectibix®Amgen Australia Pty Ltd | Metastatic colorectal cancer | To request Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the first-line treatment of RAS wild-type metastatic colorectal cancer in patients meeting certain criteria. |
| New listing(Major Submission) | PEMBROLIZUMAB50 mg injection: powder for, 1 vial100 mg injection: powder for, 1 vial Keytruda®Merck Sharp & Dohme (Australia) Pty Ltd | Melanoma | To request Section 100 (Highly Specialised Drugs) listing for the treatment of unresectable Stage III or Stage IV malignant melanoma. |
| Change to listing(Major Submission) | PNEUMOCCAL POLYSACCHARIDE CONJUGATE VACCINE (13-valent)0.5 mL injectionPrevenar 13®Pfizer Australia Pty Ltd | Pneumococcal disease | To request an extension of the use of 13-valent pneumoccoal vaccine on the National Immunisation Program for the prevention of pneumococcal disease in non-Indigenous adults aged 65 years and Indigenous adults aged 50 years. |
| New listing(Minor Submission) | POSACONAZOLE100 mg modified release tabletNoxafil®Merck Sharp & Dohme (Australia) Pty Ltd | Fungal infections | To request Authority Required listing of a new dose presentation for the same indications as those applying to the oral liquid presentation. |
| New listing(Minor Submission) | PROPRANOLOL3.75 mg/mL oral liquid,2 x 120 mLHemangiol® Pierre Fabre Australia Pty Ltd | Infantile hemangioma | To request Authority Required listing for the treatment of proliferating infantile hemangioma requiring systemic therapy. |
| New listing(Major Submission) | REGORAFENIB40 mg tablet, 84Stivarga®Bayer Australia Ltd | Gastrointestinal stromal tumours | To request Authority Required (STREAMLINED) listing for the treatment metastatic or unresectable malignant gastrointestinal stromal tumour after failure of imatinib mesylate and sunitinib treatment due to resistance or intolerance. |
| New listing(Major Submission) | RIBAVIRIN400 mg tablet, 28600 mg tablet, 28Ibavyr®Clinect Pty Ltd | Hepatitis C | To request Section 100 (Highly Specialised Drugs Program) listing for the treatment of chronic hepatitis C viral infection (genotype 2 or 3) in combination with sofosbuvir in patients 18 years or older who have compensated liver disease.  |
| New listing(Major Submission) | RITUXIMAB500 mg/50 mL injection: 1 x 50 mL vialMabThera®Roche Products Pty Ltd | Granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA) | To request Section 100 (Highly Specialised Drugs Program) listing for the induction of remission of severe active GPA and MPA in patients who are contraindicated or refractory to cyclophosphamide. |
| New listing(Major Submission) | RUXOLITINIB5 mg tablet, 5615 mg tablet, 5620 mg tablet, 56Jakavi®Novartis Pharmaceuticals Australia Pty Ltd | Myelofibrosis | To request Authority Required listing for the treatment of patients with intermediate-2 and high risk myleofibrosis with disease-related symptoms and patients with intermediate-1 risk myleofibrosis who have severe disease-related symptoms and who are intolerant, resistant or refractory to or not candidates for available therapy. |
| New listing(Major Submission) | SECUKINUMAB150 mg injection: powder for, 1 vial150 mg/1 mL injection: solution, 1 mL injection device150 mg/1 mL injection: solution, 1 mL syringeCosentyx®Novartis Pharmaceuticals Australia Pty Ltd | Severe chronic plaque psoriasis | To request Restricted Benefit listing for the treatment of severe chronic plaque psoriasis. |
| New listing(Major Submission) | SOFOSBUVIR400 mg tablet, 28Sovaldi®Gilead Sciences Pty Ltd | Hepatitis C | To request Section 100 (Highly Specialised Drugs Program) listing for the treatment of hepatitis C viral infection. |
| New listing(Major Submission) | SORAFENIB200 mg tablet, 60Nexavar®Bayer Australia Ltd | Thyroid cancer | To request Authority Required (STREAMLINED) listing for the treatment of locally advanced or metastatic progressive radioactive iodine refractory differentiated thyroid cancer. |
| New listing(Minor Submission) | SUNITINIB37.5 mg capsule, 28Sutent®Pfizer Australia Pty Ltd | Pancreatic neuroendocrine tumours, renal cell carcinoma and gastrointestinal stromal tumours | To request Authority Required listing of a new strength for the same indications as the existing 12.5 mg, 25 mg and 50 mg strengths. |
| New listing(Minor Submission) | TESTOSTERONE1% gel, 2 x 88 g pump packsTestogel® Besins Healthcare Australia Pty Ltd | Androgen deficiency | To list a new form presentation in addition to the current sachet presentation. |
| New listing(Major Submission) | TESTOSTERONE50 mg/mL cream, 50 mLAndroForte® 5Lawley Pharmaceuticals Pty Ltd | Testosterone deficiency | To request Authority Required listing for testosterone replacement therapy for symptomatic testosterone deficient males. |
| New listing(Major Submission) | TOFACITINIB5 mg tablet, 56Xeljanz®Pfizer Australia Pty Ltd | Severe active rheumatoid arthritis | To request Authority Required listing for the treatment of severe active rheumatoid arthritis. |
| New listing(Minor Submission) | TRIGLYCERIDES MEDIUM CHAIN FORMULAtriglycerides medium chain oral liquid, 8 x 500 mL cartonsNutrini Peptisorb®Nutricia Australia Pty Ltd | Medicinal food | To request restricted benefit listing for the dietary management of conditions requiring a source of medium chain triglcyerides limited to fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis, gastrointestinal disorders, radioenteritis, chemotherapy or bone marrow transplant.  |
| Change to listing(Major Submission) | VEDOLIZUMAB300 mg injection: powder for, 1 vialEntyvio®Takeda Pharmaceuticals Australia Pty Ltd | Crohn's disease | To request Section 100 (Highly Specialised Drugs Program) listing for the treatment of Crohn's disease. |
| New listing(Major Submission) | VEDOLIZUMAB300 mg injection: powder for, 1 vialEntyvio®Takeda Pharmaceuticals Australia Pty Ltd | Ulcerative colitis | To request Section 100 (Highly Specialised Drugs Program) listing for the treatment of moderate to severe ulcerative colitis. |
| Subcommittee report(DUSC Analysis) | Not applicable | Hepatitis B  | To examine the utilisation of medicines for the treatment of hepatitis B.  |
| Subcommittee report(DUSC Analysis) | Not applicable | Crohn's Disease | To examine utilisation of biological disease-modifying anti-rheumatic drugs (bDMARDs) adalimumab and infliximab for Crohn’s disease.  |
| Subcommittee report(DUSC Analysis) | Not applicable | Pulmonary Arterial Hypertension | To assess the utilisation of medicines for the treatment of pulmonary arterial hypertension (PAH). |
| Other business | Not applicable | Not applicable | To seek PBAC consideration of the draft Managed Access Programme framework which has been developed by the Access to Medicines Working Group.  |