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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 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. |

| **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  (Major Submission) | ADALIMUMAB  Injection 40 mg in 0.8 mL pre-filled syringe  Injection 40 mg in 0.8 mL pre-filled pen  Humira®  AbbVie Pty Ltd | Non-infectious intermediate, posterior or panuveitis uveitis (inflammatory disease of the eye) | To request an Authority Required listing for the treatment of vision threatening non-infectious intermediate, posterior or panuveitis uveitis. |
| New listing  (Minor Submission) | AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES  Oral powder 400 g  Neocate Junior®  Nutricia Australia Pty Ltd | The dietary management of conditions involving gastrointestinal tract impairment | To request an Authority Required listing of a drug for the treatment of cows' milk protein enteropathy, severe cows' milk protein enteropathy with failure to thrive, combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae, proven combined immunoglobulin E mediated allergy to cows' milk protein and soy protein, eosinophilic eosophagitis, cows' milk anaphylaxis. and severe intestinal malabsorption including short bowel syndrome. |
| Change to listing  (Minor Submission) | AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE  Oral liquid 130 mL, 30 Oral liquid 174 mL, 30  PKU Air®  Vitaflo Australia Pty Ltd | Phenylketonuria | To request changes to the Restricted Benefit listing of PKU Air including nutritional content and to add an additional flavour. |
| Change to listing  (Minor Submission) | AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE  Oral liquid 87 mL, 30  Oral liquid 130 mL, 30 Oral liquid 174 mL, 30  PKU Cooler®  Vitaflo Australia Pty Ltd | Phenylketonuria | To request changes to the Restricted Benefit listing of PKU Cooler including nutritional content and to add an additional flavour. |
| New listing  (Minor Submission) | AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE  Sachets containing oral powder 34 g, 30  TYR Express20®  Vitaflo Australia Pty Ltd | Tyrosinaemia | To request a Restricted Benefit listing of a new sachet size containing 20 g protein equivalent for the dietary management of tyrosinaemia. |
| New listing  (Minor Submission) | AMINO ACID FORMULA WITH VITAMINS AND MINERALS, WITHOUT PHENYLALANINE, AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID AND ARACHIDONIC ACID  Sachets containing oral powder 12.5 g, 30  PKU Anamix First Spoon®  Nutricia Australia Pty Ltd | Phenylketonuria | To request a Restricted Benefit listing for phenylketonuria. |
| Resubmission  (Minor Submission) | APREMILAST  Tablet 30 mg Pack containing 4 tablets 10 mg, 4 tablets 20 mg and 19 tablets 30 mg  Otezla®  Celgene Pty Ltd | Moderate to severe plaque psoriasis | Resubmission to request an Authority Required (STREAMLINED) listing for treatment of patients with moderate to severe plaque psoriasis. |
| Change to listing  (Minor Submission) | BOTULINUM TOXIN TYPE A  Lyophilised powder for injection 100 units  Botox®  Allergan Australia Pty Ltd | Urinary incontinence due to idiopathic overactive bladder | To request a change to listing to include prescribing by gynaecologists. |
| New listing  (Major Submission) | BREXIPIPRAZOLE  Tablet 1 mg  Tablet 2 mg  Tablet 3 mg  Tablet 4 mg  Rexulti®  Lundbeck Australia Pty Ltd | Schizophrenia | To request an Authority Required (STREAMLINED) listing for the treatment of schizophrenia. |
| New listing  (Major 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 an Authority Required (STREAMLINED) listing for treatment of partial epileptic seizures. |
| New listing  (Minor Submission) | CERTOLIZUMAB  Injection 200 mg in 1 mL single dose auto-injector  Cimzia®  UCB Australia Pty Ltd | Severe active rheumatoid arthritis, severe psoriatic arthritis, and active ankylosing spondylitis | To request an Authority Required listing of a new formulation for the treatment of severe active rheumatoid arthritis, severe psoriatic arthritis and active ankylosing spondylitis. |
| New listing  (Minor Submission) | CHORIONIC GONADOTROPIN  Injection set containing 3 vials powder for injection 1,500 units and 3 vials diluent 1 mL Injection set containing 1 vial powder for injection 5,000 units and 1 vial dileunt 1 mL  Pregnyl®  Merck Sharp & Dohme (Australia) Pty Ltd | Anovulatory infertility, infertility, combined deficiency of human growth hormone and gonadotrophins, hypogonadism or delayed puberty, and assisted reproductive technology | To request a Restricted Benefit listing of a new form of chorionic gonadotrophin for the currently listed indication. |
| Change to listing  (Minor Submission) | CRIZOTINIB  Capsule 200 mg  Capsule 250 mg  Xalkori®  Pfizer Australia Pty Ltd | Non-small cell lung cancer | To inform the PBAC of the outcome of the Managed Entry Scheme (MES) for crizotinib and to request changes to the restriction to remove the need for oncologists to register patients for the MES and to remove the grandfather restriction. |
| Change to listing  (Minor Submission) | DEGARELIX  Powder for injection 80 mg (as acetate), injection set  Powder for injection 120 mg (as acetate), injection set  Firmagon®  Ferring Pharmaceuticals Pty Ltd | Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate | To request that the Authority Required (STREAMLINED) listing be changed to a Restricted Benefit listing to be consistent with other listed gonadotropin-releasing hormone (GnRH) analogues. |
| Change to listing  (Major Submission) | dTpa VACCINE  Injection 0.5 mL  Adacel®  Sanofi-Aventis Australia Pty Ltd | Prevention of pertussis | National Immunisation Program (NIP) listing for all women in every pregnancy, primarily to reduce the risk of pertussis in newborn infants up to 2 months of age. |
| 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 Ltd | Type 2 diabetes | To request an Authority Required (STREAMLINED) listing for use as add-on therapy to metformin for the treatment of diabetes mellitus type 2. |
| Change to listing  (Major Submission) | ENZALUTAMIDE  Capsule 40 mg  Xtandi®  Astellas Pharma Australia Pty Ltd | Prostate cancer | Resubmission to request an Authority Required listing for the treatment of asymptomatic metastatic castration resistant prostate cancer in chemotherapy-naïve patients. |
| New listing  (Major Submission) | FLUTICASONE FUROATE  Powder for oral inhalation in breath actuated device containing fluticasone furoate 200 micrograms per dose  Powder for oral inhalation in breath actuated device containing fluticasone furoate 100 micrograms per dose  Arnuity Ellipta®  GlaxoSmithKline Australia Pty Ltd | Asthma | Resubmission to request fluticasone furoate to be declared as a 'drug' for the purpose of section 85(2) of the National Health Act (Cth)(Act); and the listing instruments for each Breo Ellipta, Seretide and Flixotide be amended to reflected the full name of the active component of the respective inhaled corticosteroid of each product. |
| Change to listing  (Minor Submission)  WITHDRAWN | 1. LUTROPIN ALFA 2. FOLLITROPIN WITH LUTROPIN ALFA  1. Powder for injection 75 I.U. with solvent 2. Powder for injection 150 I.U.-75 I.U. with solvent  1. Luveris® 2. Pergoveris®  Merck Serono Pty Ltd | Stimulation of follicular development | To request the addition of a General Schedule Restricted Benefit listing for the stimulation of follicular development to the current Section 100 (In-Vitro Fertilisation) Authority Required (STREAMLINED) listing. |
| New listing  (Major Submission) | MESALAZINE  Tablet (enteric coated) 800 mg  Asacol®  Baxter Healthcare Pty Ltd | Ulcerative colitis | To request an Authority Required (STREAMLINED) listing for treatment of ulcerative colitis. |
| New listing  (Major Submission) | METHOTREXATE  Injection 7.5 mg in 0.15 mL pre-filled syringe  Injection 10 mg in 0.2 mL pre-filled syringe  Injection 15 mg in 0.3 mL pre-filled syringe  Injection 20 mg in 0.4 mL pre-filled syringe  Injection 25 mg in 0.5 mL pre-filled syringe  Trexject®  Link Medical Products Pty Ltd | Rheumatoid arthritis and psoriasis | Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of rheumatoid arthritis and psoriasis for use in patients where the oral tablet form of methotrexate is unsuitable. |
| New listing  (Major Submission) | MIGALASTAT  Capsule 150 mg  Galafold®  Amicus Therapeutics | Fabry disease | To request a Section 100 (Highly Specialised Drug Program) Authority Required listing for the treatment of Fabry disease. |
| 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 | Renal cell carcinoma (RCC) | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for second-line treatment of clear cell variant renal cell carcinoma. |
| New listing  (Major Submission) | NIVOLUMAB with IPILIMUMAB  Nivolumab:  Injection concentrate for I.V. infusion 40 mg in 4 mL  Injection concentrate for I.V. infusion 100 mg in 10 mL  Ipilimumab:  Injection concentrate for I.V. infusion 50 mg in 10 mL  Injection concentrate for I.V. infusion 200 mg in 40 mL  Opdivo® with Yervoy®  Bristol-Myers Squibb Australia Pty Ltd | Metastatic melanoma | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) listing for the treatment of patients with unresectable metastatic melanoma. |
| Change to listing  (Major Submission)  WITHDRAWN | OCTREOTIDE  Injection (modified release) 10 mg (as acetate), vial and diluent syringe  Injection (modified release) 20 mg (as acetate), vial and diluent syringe  Injection (modified release) 30 mg (as acetate), vial and diluent syringe  Sandostatin® LAR®  Novartis Pharmaceuticals Australia Pty Ltd | Non-functional neuroendocrine tumours of midgut or suspected midgut origin | To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for treatment of unresectable or metastatic, well-differentiated non-functional neuroendocrine tumours. |
| New listing  (Major Submission) | PALBOCICLIB  Capsule 75 mg  Capsule 100 mg  Capsule 125 mg  Ibrance®  Pfizer Australia Pty Ltd | Hormone receptor positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer | To request an Authority Required listing with a non-steroidal aromatase inhibitor (letrozole or anastrozole) as initial endocrine-based therapy in postmenopausal women with hormone receptor positive, HER2 negative advanced breast cancer. |
| Change to listing  (Major Submission) | PEMBROLIZUMAB  Injection concentrate for I.V. infusion 100 mg in 4 mL  Powder for injection 50 mg  Keytruda®  Merck Sharp and Dohme (Australia) | Non-small cell lung cancer | To request a listing under Section 100 (Efficient Funding of Chemotherapy) as first line monotherapy in patients expressing PD-L1 for non-small cell lung cancer. |
| Change to listing  (Minor Submission) | POMALIDOMIDE  Capsule 3 mg Capsule 4 mg  Pomalyst®  Celgene Pty Ltd | Relapsed/refractory multiple myeloma (RRMM) | To request an amendment to the Section 100 (Highly Specialised Drugs) listing to include patients with relapsed or refractory multiple myeloma who have received treatment with both lenalidomide and bortezomib and have experienced severe intolerance or toxicity unresponsive to adjusted dose or scheduling of lenalidomide and/or bortezomib. |
| Change to listing  (Minor Submission)  WITHDRAWN | PROGESTERONE  Vaginal gel (prolonged release) 90 mg in single dose pre-filled applicator  Crinone®  Merck Serono Australia Pty Ltd | Assisted reproductive technology | To request a change to the Section 100 (In-Vitro Fertilisation) listing to include the MBS item 13215 in the PBS restriction, to allow use in 'thaw' IVF cycles. |
| New listing  (Major Submission) | RANOLAZINE  Tablet (modified release) 375 mg  Tablet (modified release) 500 mg  Tablet (modified release) 750 mg  Ranexa®  Menarini Australia Pty Ltd | Stable angina pectoris | To request an Authority Required (STREAMLINED) listing as an add-on therapy for the symptomatic treatment of stable angina pectoris. |
| New listing  (Minor Submission) | RITUXIMAB  Solution for subcutaneous injection 1600 mg in 13.4 mL  MabThera SC®  Roche Products Pty Ltd | Chronic lymphocytic leukaemia (CLL) | To request a General Schedule and Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing of a new presentation of rituximab for the treatment of CLL. |
| New listing  (Major Submission) | SELEXIPAG  Tablet 200 mcg  Tablet 400 mcg  Tablet 600 mcg  Tablet 800 mcg  Tablet 1000 mcg  Tablet 1200 mcg  Tablet 1400 mcg  Tablet 1600 mcg  Uptravi®  Actelion Pharmaceuticals Australia Pty Ltd | Pulmonary arterial hypertension | Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required listing as an add-on therapy for the treatment of pulmonary arterial hypertension. |
| New listing  (Major Submission) | TENOFOVIR ALAFENAMIDE  Tablet 25 mg  Vemlidy®  Gilead Sciences Pty Ltd | Chronic hepatitis B | To request an Authority Required (STREAMLINED) listing for the treatment of chronic hepatitis B infection. |
| New listing  (Major Submission) | TOLVAPTAN  Tablet 15 mg  Tablet 30 mg  Pack containing 28 tablets 15 mg and 28 tablets 45 mg  Pack containing 28 tablets 30 mg and 28 tablets 60 mg  Pack containing 28 tablets 30 mg and 28 tablets 90 mg  Jinarc®  Otsuka Australia Pharmaceutical Pty Ltd | Autosomal dominant polycystic kidney disease | To request an Authority Required listing for the treatment of autosomal dominant polycystic kidney disease. |
| 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 | A resubmission to request an Authority Required (STREAMLINED) listing for the treatment of metastatic colorectal cancer. |
| Change to listing  (Minor Submission) | 1. TRIGLYCERIDES LONG CHAIN  2. MEDIUM CHAIN TRIGLYCERIDES  1. Oral liquid 250 mL, 18 (Carbzero) 2. Oral liquid 250 mL, 18 (Betaquik)  1. CarbZero® 2. Betaquik®  Vitaflo Australia Pty Ltd | 1. Ketogenic diet 2. Ketogenic diet; dietary management of conditions requiring a source of medium chain triglycerides | To request a change in nutritional profile and packaging for CarbZero® and Betaquik®. |
| New listing  (Major Submission) | ULIPRISTAL  Tablet 5 mg  Esmya®  Vifor Pharma Pty Ltd | Moderate to severe symptoms of uterine fibroids | Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of moderate to severe symptoms of uterine fibroids in women of reproductive age. |
| New listing  (Minor Submission) | URSODEOXYCHOLIC ACID  Tablet 500 mg  Ursofalk®  Orphan Australia Pty Ltd | Primary biliary cirrhosis | To request an Authority Required (STREAMLINED) listing of a new strength for the treatment of primary biliary cirrhosis |
| Change to listing  (Major Submission) | USTEKINUMAB  Injection concentrate for I.V. infusion 130 mg in 26 mL  Injection 45 mg in 0.5 mL  Stelara®  Janssen-Cilag Pty Ltd | Crohn disease | To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the single intravenous induction dose and a Section 85 Authority Required listing for all subcutaneous doses thereafter for the treatment of severe Crohn disease and complex refractory fistulating Crohn disease. |
| New listing  (Major Submission) | VENETOCLAX  Tablet 10 mg  Tablet 50 mg  Tablet 100 mg  Venclexta®  AbbVie Pty Ltd | Relapsed/refractory chronic lymphoid leukaemia (CLL) | To request an Authority Required listing for the treatment of relapsed/refractory CLL. |
| Sub-committee report  (DUSC analysis) | Imatinib  Glivec®  Alphapharm Pty Ltd | Gastrointestinal stromal tumour (GIST) | To compare the predicted versus actual use of imatinib for GIST 24 months after the listing was extended to allow an increase in its total treatment duration from 12 months to 36 months. |
| Sub-committee report  (DUSC analysis) | Everolimus  Afinitor®  Novartis Pharmaceuticals Australia Pty Ltd | Metastatic breast cancer | To compare the predicted versus actual use of everolimus for metastatic breast cancer. |
| Sub-committee report  (DUSC analysis) | Everolimus  Afinitor®  Novartis Pharmaceuticals Australia Pty Ltd | Tuberous sclerosis complex | To compare the predicted versus actual use of everolimus for tuberous sclerosis complex (TSC). |
| Sub-committee report  (DUSC analysis) | Ferric carboxymaltose  Ferinject®  Vifor Pharma Pty Ltd | Iron deficiency anaemia | To compare the predicted versus actual use of ferric carboxymaltose 24 months after its PBS listing |
| Sub-committee report  (DUSC analysis) | Erlotinib, Tarceva®, Roche Products Pty Ltd  Gefitinib, Iressa®, AstraZeneca Pty Ltd | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer | To compare the predicted versus actual use of the tyrosine kinase inhibitors, erlotinib and gefitinib. |
| Sub-committee report  (DUSC analysis) | Metformin  Metformin+glibenclamide  Glibenclamide  Gliclazide  Glimepiride  Glipizide  Pioglitazone  Rosiglitazone  Rosiglitazone+metformin  Alogliptin  Alogliptin+metformin  Linagliptin  Linagliptin+metformin  Saxagliptin  Saxagliptin+metformin  Sitagliptin  Sitagliptin+metformin  Vildagliptin  Vildagliptin+metformin  Exenatide  Dapagliflozin  Dapagliflozine+metformin  Empagliflozin+metformin  EmpagliflozinAcarbose  Insulin and analogues  (all current and previously listed brands including generic versions) | Diabetes | To review the utilisation of medicines used to treat diabetes. |