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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. |

| **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  (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. |
| 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. |
| 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. |
| 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. |
| 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. |
| 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. |
| 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. |
| 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. |
| 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 |
| Change to listing  (Major Submission) | EMPAGLIFLOZIN   10 mg tablet, 30  25 mg tablet, 30  Jardiance®  Boehringer Ingelheim | 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) | EMPAGLIFLOZIN with METFORMIN  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  TBC  Boehringer Ingelheim | 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. |
| 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. |
| 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. |
| 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. |
| 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 |
| 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. |
| 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) |
| 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 nanparticle 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. |
| 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. |
| 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. |
| 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. |
| Change to listing  (Minor Submission) | PROPRANOLOL  3.75 mg/mL oral liquid,2 x 120 mL   Hemangiol®   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. |
| 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 releasse, 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. |
| Change to listing  (Minor Submission) | SITAGLIPTIN SITAGLIPTIN and METFORMIN SITAGLIPTIN and METFORMIN XR  sitagliptin 100 mg tablet, 28 sitagliptin 50 mg tablet, 28 sitagliptin 25 mg tablet, 28  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   sitagliptin 100 mg + metformin hydrochloride 1000 mg tablet: modified release, 28 sitagliptin 50 mg + metformin hydrochloride 1000 mg tablet: modified release, 56   Januvia® Janumet®  Janumet XR®  Merck Sharp & Dohme (Australia) Pty Limited | 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. |
| Change to listing  (Major Submission) | SORAFENIB  200 mg tablet, 120  Nexavar®  Bayer Australia Ltd | Differentiated thyroid cancer | 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). |
| New listing  (Minor Submission) | THYROXINE SODIUM  25 microgram tablet, 200 50 microgram tablet, 200 75 microgram tablet, 200 100 microgram tablet, 200 125 microgram tablet, 200 200 microgram tablet, 200  Eltroxin®  Aspen Pharmacare Australia Pty Ltd | Thyroid hormone deficiency | To request Unrestricted benefit listing of a new brand and additional strengths of thyroxine sodium. |
| New listing  (Minor Submission) | TRIGLYCERIDES MEDIUM CHAIN  oral liquid, 12 x 500 mL pouches  Peptamen Junior Liquid  Peptamen Junior Advance  Nestlé Health Science (Nestlé Australia Ltd) | 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) | TRIGLYCERIDES MEDIUM CHAIN   oral liquid: powder for, 400 g  Monogen®  Nutricia Australia Pty Ltd | Medicinal food | To advise the PBAC and Nutritional Products Working Party of an upgrade to the formulation. |
| 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 ipilmumab 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 |
| 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) |