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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.
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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 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 listingChange to recommended listing(Major Submission) | AFLIBERCEPTSolution for intravitreal injection 4 mg in 100 microlitres (40 mg per mL) vial Solution for intravitreal injection 4 mg in 100 microlitres (40 mg per mL) pre-filled syringeEylea® Bayer Australia Ltd | Subfoveal choroidal neovascularisation | To request an Authority Required listing for the treatment of patients with subfoveal choroidal neovascularisation secondary to pathologic myopia. |
| New listing(Minor Submission) | AMINO ACID FORMULA WITH VITAMINS AND MINERALS, LOW PHENYLALANINE AND SUPPLEMENTED WITH DOCOSAHEXAENOIC ACID AND ARACHIDONIC ACID Sachets containing oral powder 12.5 g, 30 (PKU Explore 5)Sachets containing oral powder 25 g, 30 (PKU Explore 10)PKU Explore®Vitaflo Australia Pty Ltd | Phenylketonuria (PKU) | To request a Restricted Benefit listing for the dietary management of PKU. |
| New listing(Major Submission) | APALUTAMIDETablet 60 mg Erlyand®Janssen-Cilag Pty Ltd  | Castration resistant prostate cancer | Resubmission to request an Authority Required listing for the treatment of non-metastatic castration resistant prostate cancer in combination with androgen deprivation therapy.  |
| Change to listing(Major Submission) | ATEZOLIZUMABSolution concentrate for I.V. infusion 1200 mg in 20 mLTecentriq®Roche Products Pty Ltd | Small cell lung cancer | To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first-line treatment of patients with extensive-stage small cell lung cancer.  |
| New listing(Major Submission) | BEZLOTOXUMABSolution concentrate for I.V. infusion 1000 mg in 40 mLZinplava®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 two or more risk factors for CDI recurrence. |
| Change to listing(Minor Submission) | BLINATUMOMABPowder for I.V. infusion 38.5 microgramsBlincyto®Amgen Australia Pty Limited | Acute lymphoblastic leukaemia (ALL) | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of B‑cell precursor ALL in patients with haematological complete remission with minimal residual disease following chemotherapy. |
| Change to listing(Major Submission) | BUDESONIDE WITH FORMOTEROLPowder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses;Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 dosesSymbicort® Turbuhaler® 200/6;Symbicort® Rapihaler® 100/3AstraZeneca Pty Ltd | Asthma | To request an Authority Required (STREAMLINED) listing for use as first-line treatment of mild asthma. |
| Change to listing(Major Submission) | CABOZANTINIBTablet 20 mgTablet 40 mgTablet 60 mgCabometyx®Ipsen Pty Ltd | Hepatocellular carcinoma | To request an Authority Required (STREAMLINED) listing for the treatment of patients with hepatocellular carcinoma who have previously been treated with sorafenib for this condition. |
| Change to recommended listing(Minor Submission) | CARMELLOSEEye drops containing carmellose sodium 5 mg per mL, 10 mLEvolve® carmelloseHYPROMELLOSEEye drops containing hypromellose 3 mg per mL, 10 mLEvolve® hypromelloseContact Lens Centre Australia Ltd | Severe dry eye syndrome | Resubmission to request an Authority Required (STREAMLINED) listing for treatment of severe dry eye syndrome. |
| New listing(Minor Submission) | CINACALCETTablet 30 mgTablet 60 mgTablet 90 mgPharmacor Cinacalcet®Pharmacor Pty Limited | Chronic kidney disease (CKD) | To request an Authority Required (STREAMLINED) listing of cinacalcet for the treatment of patients with secondary hyperparathyroidism in CKD. |
| Change to listing(Major Submission) | CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX Lyophilised powder for I.M. injection 300 unitsLyophilised powder for I.M. injection 500 unitsDysport®Ipsen Pty Ltd | Focal spasticity of the lower limb  | Resubmission to request a Section 100 (Botulinum Toxin Program) Authority Required (STREAMLINED) listing for the treatment of patients with moderate to severe focal spasticity of the lower limb following stroke. |
| Change to listing(Minor Submission) | DABRAFENIB and TRAMETINIBDabrafenib:Capsule 50 mgCapsule 75 mgTrametinib:Tablet 500 microgramTablet 2 mgTafinlar® andMekinist®Novartis Pharmaceuticals Australia Pty Ltd | Melanoma | Resubmission to request an Authority Required (STREAMLINED) listing for the adjuvant treatment of patients who have had completely surgically resected BRAF V600 mutation positive Stage III malignant melanoma.  |
| Change to listing(Major Submission) | DENOSUMABInjection 120 mg in 1.7 mLXgeva®Amgen Australia Pty Ltd | Multiple myeloma | Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with multiple myeloma who have renal impairment. |
| New listing(Major Submission) | DOLUTEGRAVIR WITH LAMIVUDINETablet containing dolutegravir 50 mg (as sodium) with lamivudine 300 mgDovato®ViiV Healthcare Pty Ltd | Human immunodeficiency virus (HIV) infection | To request a Section 100 (Highly Specialised Drugs Program - Community Access) Authority Required (STREAMLINED) listing for the treatment of patients with HIV infection. |
| New listing(Major Submission) | DUPILUMABInjection 300 mg in 2 mL single use pre-filled syringeDupixent®sanofi-aventis Australia Pty Ltd | Atopic dermatitis | Resubmission to request an Authority Required listing for the treatment of chronic, moderate to severe, atopic dermatitis in patients who have had an inadequate response to topical therapies. |
| New listing(Major Submission) | DURVALUMABSolution concentrate for I.V. infusion 120 mg in 2.4 mLSolution concentrate for I.V. infusion 500 mg in 10 mLImfinziTMAstraZeneca Pty Ltd | Urothelial cancer | To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of locally advanced or metastatic urothelial cancer after the failure of a prior platinum-based chemotherapy. |
| New listing(Major Submission) | DURVALUMABSolution concentrate for I.V. infusion 120 mg in 2.4 mLSolution concentrate for I.V. infusion 500 mg in 10 mLImfinziTMAstraZeneca Pty Ltd | Non-small cell lung cancer (NSCLC)  | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of patients with unresectable Stage III NSCLC whose disease has not progressed following platinum-based chemoradiation therapy. |
| New listing(Minor Submission) | ENOXAPARINInjection containing enoxaparin sodium 120 mg (12,000 I.U. anti-Xa) in 0.8 mL pre-filled syringeInjection containing enoxaparin sodium 150 mg (15,000 I.U. anti-Xa) in 1 mL pre-filled syringeClexane Forte®Enoxaparin Winthrop®Clexane Forte Safety-Lock®Sanofi-aventis Australia Pty Ltd | Deep vein thrombosis (DVT) | To request unrestricted benefit listings of two new strengths of enoxaparin pre-filled syringes. |
| Change to listing(Major Submission) | EVOLOCUMABInjection 420 mg in 3.5 mL single use pre-filled cartridge Injection 140 mg in 1 mL single use pre-filled pen Repatha®Amgen Australia Pty Ltd | Hypercholesterolaemia | Resubmission to request an Authority Required listing for the treatment of patients with hypercholesterolaemia who are very high risk and symptomatic for atherosclerotic cardiovascular disease and who are inadequately controlled on optimal doses of high potency statins and ezetimibe. |
| New listing(Minor Submission) | FERRIC DERISOMALTOSEInjection 1000 mg (iron) in 10 mLInjection 500 mg (iron) in 5 mLMonofer®Pfizer Australia Pty Ltd | Iron deficiency anaemia | To request an unrestricted benefit listing for a new strength of ferric derisomaltose and to request a change in the maximum quantity and repeats for the currently listed 500 mg strength of ferric derisomaltose. |
| New listing(Minor Submission) | FINGOLIMODCapsule 250 micrograms (as hydrochloride)Gilenya®Novartis Pharmaceuticals Australia Pty Ltd | Relapsing-remitting multiple sclerosis (RRMS) | To request an Authority Required listing of a new strength of fingolimod capsules for patients with RRMS who weigh 40kg or less, including paediatric patients. |
| New listing(Minor Submission) | FLUTICASONE FUROATEPowder for oral inhalation in breath actuated device containing fluticasone furoate 50 micrograms per dose, 30 dosesArnuity Ellipta®GlaxoSmithKline Australia Pty Ltd | Asthma | To request an Unrestricted Benefit listing for a new strength of fluticasone furoate.  |
| New listing(Major Submission) | GALCANEZUMABInjection 120 mg in 1 mL single use pre-filled penEmgality®Eli Lilly Australia Pty Ltd | Chronic migraine | To request an Authority Required (STREAMLINED) listing for the prophylactic treatment of patients with chronic migraine who have experienced inadequate response, intolerance or a contraindication to at least three prior preventive migraine medications. |
| New listing(Minor Submission)*Withdrawn* | GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALSSachets containing oral powder 28g, 30Tylactin Build 20®Cortex Health Pty Ltd | Tyrosinaemia | To request a Restricted Benefit listing for the dietary management of patients with tyrosinaemia. |
| New listing(Minor Submission) | GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALSSachets containing oral powder 35 g, 30 (TYR Sphere 20)TYR Sphere 20®Vitaflo Australia Pty Ltd | Tyrosinaemia | To request a Restricted Benefit listing for the dietary management of patients with tyrosinaemia. |
| New listing(Minor Submission) | GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID WITH LOW PHENYLALANINEOral liquid 250 mL, 18PKU GMPro LQ®Nutricia Australia Pty Ltd | Phenylketonuria (PKU) | To request a Restricted Benefit listing for the dietary management of PKU. |
| New listing and change to listing(Major Submission) | INFLUENZA QUADRIVALENT ADJUVANTED VACCINE Injection 0.5 mLFluad® QuadINFLUENZA TRIVALENT ADJUVANTED VACCINEInjection 0.5 mLFluad®Seqirus (Australia) Pty Ltd | Prevention of seasonal influenza | To request National Immunisation Program (NIP) listing for the prevention of seasonal influenza in patients aged 65 years and over; and to request that the PBAC review the circumstances of the recommended NIP listing for Fluad® influenza trivalent adjuvanted vaccine for the prevention of seasonal influenza in patients aged 65 years and over.  |
| New listing(Major Submission) | INFLUENZA QUADRIVALENT VACCINEInjection 0.5 mLVaxigrip TetraTMsanofi-aventis Australia Pty Ltd | Prevention of seasonal influenza | To request listing on the National Immunisation Program (NIP) for the population already eligible for seasonal influenza vaccination with other brands of influenza vaccine and to extend the population eligible for seasonal influenza vaccination through the NIP to include all children aged 6 months to <5 years. |
| New listing(Major Submission) | LANADELUMABSolution for injection 300 mg in 2 mL Takhzyro®Shire Australia Pty Ltd | Hereditary angioedema | To request an Authority Required listing for the prevention of recurrent attacks of hereditary anioedema (C1-esterase-inhibitor deficiency or dysfunction) in patients aged 12 years and older for whom the use of danazol is not clinically appropriate or not effective. |
| Change to listing(Minor Submission) | LENALIDOMIDECapsule 5 mgCapsule 10 mgCapsule 15 mgRevlimid®Celgene Pty Ltd | Multiple myeloma | Resubmission to request an extension to the Section 100 (Highly Specialised Drug Program) Authority Required listing to include maintenance treatment of patients with newly diagnosed multiple myeloma who have undergone an autologous stem cell transplant.  |
| New listing(Major Submission) | LEUPRORELINSubcutaneous implant 3.6 mg (as acetate) in pre-filled syringeSubcutaneous implant 5 mg (as acetate) in pre-filled syringeLerin® Sandoz Pty Ltd | Prostate cancer | To request a Restricted Benefit listing for the treatment of patients with locally advanced (Stage C) and metastatic (Stage D) prostate cancer. |
| New listing(Minor Submission) | LISDEXAMFETAMINECapsule containing lisdexamfetamine dimesilate 20 mgCapsule containing lisdexamfetamine dimesilate 40 mgCapsule containing lisdexamfetamine dimesilate 60 mgVyvanse®Shire Australia Pty Ltd | Attention deficit hyperactivity disorder (ADHD) | To request Authority Required listings for three new strengths of lisdexamfetamine for the treatment of ADHD. |
| New listing(Major Submission) | LUMACAFTOR WITH IVACAFTORSachet containing granules, lumacaftor 100 mg with ivacaftor 125 mgSachet containing granules, lumacaftor 150 mg with ivacaftor 188 mgOrkambi®Vertex Pharmaceuticals (Australia) Pty Ltd | Cystic fibrosis | To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of patients aged 2 years or older who are homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator gene. |
| New listing(Minor Submission) | MUPIROCINNasal ointment 20 mg (as calcium) per gram, 5 gMedsurge Mupirocin Nasal Ointment®Medsurge Healthcare Pty Ltd | *Staphylococcus aureus* infection | To request an Authority Required (STREAMLINED) listing for a new pack size of mupirocin nasal ointment for the treatment of Aboriginal or Torres Strait Islander persons with *Staphylococcus aureus* (golden staph) infection of the nasal cavity. |
| Change to listing(Minor Submission) | NATALIZUMABSolution concentrate for I.V. infusion 300 mg in 15 mLTysabri®Biogen Australia Pty Ltd | Relapsing-remitting multiple sclerosis (RRMS) | To request the removal of age restrictions from the existing listing for the treatment of RRMS to permit use of natalizumab in all ages. |
| Change to listing(Minor Submission) | NIVOLUMABInjection concentrate for I.V. infusion 40 mg in 4 mLInjection concentrate for I.V. infusion 100 mg in 10 mLOpdivo®Bristol-Myers Squibb Australia Pty Ltd | Melanoma | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program), Authority Required (STREAMLINED) listing for the adjuvant treatment of patients who have had completely surgically resected Stage III or Stage IV malignant melanoma. |
| Change to listing(Major Submission) | NUSINERSEN Solution for injection 12 mg in 5 mLSpinraza®Biogen Australia Pty Ltd | Spinal muscular atrophy | To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of patients with pre-symptomatic, infantile and childhood-onset, spinal muscular atrophy. |
| New listing(Major Submission) | OBETICHOLIC ACIDTablet 5 mgTablet 10 mgOcaliva®Emerge Health Pty Ltd | Primary biliary cholangitis | Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with primary biliary cholangitis. |
| Change to listing(Major Submission) | OCTREOTIDEInjection (modified release) 30 mg (as acetate), vial and diluent syringe Sandostatin®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 (STREAMLINED) listing for the treatment of unresectable locally advanced or metastatic, non-functional neuroendocrine tumours of midgut or suspected midgut origin. |
| Change to listing(Major Submission) | OSIMERTINIBTablet 40 mgTablet 80 mgTagrisso®AstraZeneca Pty Ltd | Non-small cell lung cancer (NSCLC)  | To request an Authority Required listing for the first-line treatment of patients with Stage IIIB (locally advanced) or Stage IV (metastatic), epidermal growth factor receptor mutation positive NSCLC. |
| Change to listing(Major Submission) | OXYCODONETablet containing oxycodone hydrochloride 10 mg (controlled release) Tablet containing oxycodone hydrochloride 15 mg (controlled release) Tablet containing oxycodone hydrochloride 20 mg (controlled release) Tablet containing oxycodone hydrochloride 30 mg (controlled release) Tablet containing oxycodone hydrochloride 40 mg (controlled release) Tablet containing oxycodone hydrochloride 80 mg (controlled release)OxyContin®Mundipharma Pty Limited | Chronic severe disabling pain | Resubmission to request changes to the authority level and restriction for the existing a-flagged listings for controlled release oxycodone for chronic severe disabling pain to differentiate the brands that are intended to be crush-deterrent. |
| New listing(Minor Submission) | OXYCODONECapsule containing oxycodone hydrochloride 5 mg, 10OxyNorm®Mundipharma Pty Limited | Severe disabling pain | To request a Restricted Benefit listing for a new pack size of oxycodone. |
| Change to listing(Major Submission) | PEMBROLIZUMABSolution concentrate for I.V. infusion 100 mg in 4 mLKeytruda®Merck Sharp & Dohme (Australia) Pty Ltd | Melanoma | Resubmission to request Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the adjuvant treatment of patients who have had completely surgically resected Stage III malignant melanoma.  |
| Change to listing(Major Submission) | PEMBROLIZUMABSolution concentrate for I.V. infusion 100 mg in 4 mLKeytruda®Merck Sharp & Dohme (Australia) Pty Ltd | Non-small cell lung cancer (NSCLC) | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing, in combination with platinum chemotherapy and pemetrexed, for the first-line treatment of Stage IV non-squamous non-small cell lung cancer. |
| New listing(Major Submission) | PLITIDEPSINPowder for I.V. infusion 2 mg with 4 mL solventAplidin®Specialised Therapeutics Pharma Pty Ltd  | Multiple myeloma | To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required listing in combination with dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who meet certain conditions.  |
| Change to listing(Major Submission) | POMALIDOMIDECapsule 3 mgCapsule 4 mgPomalyst®Celgene Pty Ltd | Multiple myeloma | To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing in combination with bortezomib and dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received at least one prior treatment regimen (including lenalidomide). |
| Change to recommended listing(Minor Submission) | RAMUCIRUMAB100 mg in 10 mL vial, 500 mg in 50 mL vialCyramza®Eli Lilly Australia Pty Ltd | Advanced or metastatic gastric or gastro-oesophageal junction adenocarcinoma | Resubmission to request reconsideration of the recommended Authority Required (STREAMLINED) listing in combination with paclitaxel for treament of advanced or metastatic gastric or gastro-oesophageal junction adenocarcinoma. Ramucirumab was recommended by the PBAC at its March 2018 meeting. |
| New listing(Minor Submission) | REGORAFENIBTablet 40 mg (as monohydrate)Stivarga®Bayer Australia Ltd | Hepatocellular carcinoma (HCC) | Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with unresectable HCC who have progressed on prior tyrosine kinase inhibitor treatment. |
| Change to listing(Minor Submission) | RIFAXIMINTablet 550 mgXifaxan®Norgine Pty Ltd | Prevention of hepatic encephalopathy | To request a change to the existing listing from Authority Required (Telephone) to Authority Required (STREAMLINED). |
| New listing(Major Submission) | RISANKIZUMAB Injection 75 mg in 0.83 mL pre-filled syringeSkyrizi®AbbVie Pty Ltd | Chronic plaque psoriasis | To request an Authority Required listing for the treatment of severe chronic plaque psoriasis. |
| New listing(Major Submission) | ROMOSOZUMABInjection 105 mg in 1.17 mL single use pre-filled syringeInjection 105 mg in 1.17 mL single use pre-filled penEvenity®Amgen Australia Pty Ltd | Severe osteoporosis | Resubmission to request an Authority Required listing for the treatment of severe osteoporosis. |
| New listing(Minor Submission) | SAPROPTERINPowder for oral liquid 100 mg (as dihydrochloride),Powder for oral liquid 500 mg (as dihydrochloride)Kuvan®BioMarin Pharmaceutical Australia Pty Ltd | Hyperphenylalaninaemia (HPA) | To request the Authority Required listing of two new forms of sapropterin for the treatment of HPA in patients with tetrahydrobiopterin (BH4) deficiency; and in patients with phenylketonuria (PKU). |
| Change to listing(Minor Submission) | SAPROPTERINTablet (soluble) containing sapropterin dihydrochloride 100 mgKuvan®BioMarin Pharmaceutical Australia Pty Ltd | Hyperphenylalaninaemia (HPA) | To request a change to the existing listing from Authority Required (Written) to Authority Required (Telephone) for the treatment of HPA in patients with tetrahydrobiopterin (BH4) deficiency. |
| New listing(Minor Submission) | SODIUM PHENYLBUTYRATEGranules 483 mg (as sodium) per g, 174 gPheburane®Orpharma Pty Ltd | Urea cycle disorder (UCD) | Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with UCD. |
| New listing(Minor Submission) | TRASTUZUMABPowder for I.V. infusion 150 mgHerzuma®Celltrion Healthcare Australia Pty Ltd. | Breast cancerGastric cancer | To request a Section 100 (Efficient Funding of Chemotherapy Program), Authority Required (STREAMLINED) listing of a biosimilar trastuzumab under the same conditions as the reference biologic. |
| New listing(Minor Submission) | TRASTUZUMABPowder for I.V. infusion 60 mgPowder for I.V. infusion 150 mgPowder for I.V. infusion 420 mgKanjinti®Amgen Australia Pty Ltd | Breast cancer,Gastric cancer | To request a Section 100 (Efficient Funding of Chemotherapy Program), Authority Required (STREAMLINED) listing of a biosimilar trastuzumab under the same conditions as the reference biologic. |
| Change to listing(Minor Submission) | TYROSINE WITH CARBOHYDRATESachets of oral powder 4 g containing 1 g tyrosine, 30 (Tyrosine 1000)Tyrosine 1000®Vitaflo Australia Pty Ltd | Phenylketonuria (PKU) | To request a change to the existing listing to reflect a change in the recommended age indication from "suitable from birth” to “suitable from 3 years of age” due to product formulation changes. |
| Sub-committee report (DUSC Analysis) | ARMODAFINILNuvigil®Teva Pharma Australia Pty Limited | Narcolepsy | To compare the predicted and actual use of armodafinil for the treatment of narcolepsy since PBS listing for this indication. Use of dexamfetamine and modafinil for this indication will also be reported. |
| Sub-committee report(DUSC Analysis) | Gonadotrophin-releasing hormone (GnRH) agonists:GoserelinZoladex®, AstraZeneca Pty LtdGoserelin AND BicalutamideZolaCos®, AstraZeneca Pty LtdLeuprorelin Lucrin®, AbbVie Pty LtdEligard®, Mundipharma Pty LimitedNafarelin Synarel®, Pfizer Australia Pty LtdTriptorelin Diphereline®, Ipsen Pty Ltd | Carcinoma of the prostate, central precocious puberty, breast cancer, endometriosis, and anticipated premature ovarian failure. | To review the use of gonadotrophin‑releasing hormone (GnRH) agonists for the treatment of carcinoma of the prostate, central precocious puberty, breast cancer, endometriosis, and anticipated premature ovarian failure. The analysis will not include use of these medicines for in-vitro fertilisation (IVF).  |
| Sub-committee report(DUSC Analysis) | SapropterinKuvan®BioMarin Pharmaceutical Australia Pty Ltd | Hyperphenylalaninaemia (HPA) due to tetrahydrobiopterin (BH4) deficiency | To compare the predicted and actual use of sapropterin for the treatment of HPA due to BH4 deficiency since PBS listing for this indication. |
| Cost-effectiveness review of pneumococcal vaccines for the National Immunisation Program (NIP). | PNEUMOCOCCAL VACCINESPneumovax 23® Seqirus Australia Pty Ltd Prevenar 13®Pfizer Australia Pty Ltd | Vaccines for the prevention of pneumococcal disease | To consider the eligible populations for vaccination with a 23-valent pneumococcal polysaccharide vaccine (23vPPV) and or 13-valent pneumococcal conjugate vaccine (13vPCV) via the National Immunisation Program (NIP). |