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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.
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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) | AMINO ACID FORMULA with FAT, CARBOHYDRATE, VITAMINS, MINERALS and TRACE ELEMENTS without PHENYLALANINEBottles containing oral powder 34 g, 30PKU EASY® SHAKE & GOAMINO ACID FORMULA with FAT, CARBOHYDRATE without PHENYLALANINETablet: modified release, 70.8 g protein per 100 g, 110 g PKU EASY® MICROTABS PROTEIN FORMULA with AMINO ACIDS, CARBOHYDRATES, VITAMINS and MINERALS without PHENYLALANINE, and SUPPLEMENTED with DOCOSAHEXAENOIC ACIDOral liquid 130 mL, 30 PKU EASY®Orpharma Pty Ltd | Phenylketonuria | To request an increase in maximum quantities for PKU EASY SHAKE & GO, PKU EASY MICROTABS, and PKU EASY. |
| Change to listing(Major Submission) | ADALIMUMABInjection 40 mg in 0.8 mL pre-filled penInjection 40 mg in 0.8 mL pre-filled syringeHumira®AbbVie Pty Ltd | Hidradenitis suppurativa | Resubmission to request an Authority Required listing for the treatment of moderate to severe hidradenitis suppurativa. |
| New listing(Minor Submission) | APOMORPHINEInjection containing apomorphine (as hydrochloride) 100 mg in 20 mLApomine®Pfizer Australia Pty Ltd | Parkinson disease  | To request a General Schedule and Section 100 (Highly Specialised Drugs Program) listing of an additional strength of apomorphine. |
| New listing(Major Submission) | APREMILASTTablet 30 mgPack containing 4 tablets 10 mg, 4 tablets 20 mg and 19 tablets 30 mgOtezla®Celgene Pty Ltd | Plaque psoriasis | Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of moderate to severe plaque psoriasis. |
| Change to recommended listing(Minor Submission) | BLINATUMOMABInjection 38.5 microgram [1 vial] and inert substance solution [10 mL vial]Blincyto® Amgen Australia Pty Ltd | Relapsed or refractory Philadelphia-chromosome negative B-precursor acute lymphoblastic leukaemia | Resubmission to request a revision to the July 2016 PBAC recommendation. |
| Change to listing(Major Submission) | BRENTUXIMAB VEDOTINPowder for I.V. infusion 50 mgAdcetris®Takeda Pharmaceuticals Australia Pty Ltd | Hodgkin lymphoma | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of relapsed or refractory Hodgkin lymphoma for autologous stem cell transplant-naïve patients. |
| Change to listing(Major Submission) | BRENTUXIMAB VEDOTINPowder for I.V. infusion 50 mgAdcetris®Takeda Pharmaceuticals Australia Pty Ltd | Hodgkin lymphoma | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of relapsed or refractory Hodgkin lymphoma following autologous stem cell transplant failure. |
| New listing(Major Submission) | CALCIPOTRIOL with BETAMETHASONEFoam containing calcipotriol 50 micrograms with betamethasone 500 micrograms (as dipropionate) per g, 60 gEnstilar®LEO Pharma Pty Ltd | Psoriasis | To request a Restricted Benefit listing for patients with chronic stable plaque type psoriasis vulgaris that is inadequately controlled with either a Vitamin D analogue or potent topical corticosteroid monotherapy. |
| New listing(Major Submission) | CARFILZOMIBPowder for I.V. infusion 30 mgPowder for I.V. infusion 60 mgKyprolis®Amgen Australia Pty Ltd | Multiple myeloma | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of multiple myeloma in patients failing one prior line of treatment. |
| New listing(Major Submission) | CERITINIBCapsule 150 mgZykadia®Novartis Pharmaceuticals Australia Pty Ltd | Non-small cell lung cancer (NSCLC) | To request an Authority Required listing for anaplastic lymphoma kinase (ALK)-positive locally advanced or metastatic NSCLC patients with disease progression, following treatment with a prior ALK inhibitor. |
| New listing(Minor Submission) | CETUXIMABInjection 100 mg in 20 mLInjection 500 mg in 100 mLErbitux®Merck Serono Australia Pty Ltd  | Recurrent or metastatic squamous cell carcinoma of the head and neck | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of recurrent or metastatic squamous cell carcinoma of the head and neck. |
| New listing(Major Submission)WITHDRAWN | EDOXABANTablet 30 mgTablet 60 mgLixiana®Daiichi Sankyo Pty Ltd | Prevention of stroke or systemic embolism in patients with non-valvular atrial fibrillation (NVAF) | To request an Authority Required (STREAMLINED) listing for prevention of stroke or systemic embolism in patients with NVAF. |
| New listing(Major Submission)WITHDRAWN | EDOXABANTablet 30 mgTablet 60 mgLixiana®Daiichi Sankyo Pty Ltd | Deep vein thrombosis (DVT) and pulmonary embolism (PE) (venous thromboembolism) | To request an Authority Required (STREAMLINED) listing for treatment of DVT and PE. |
| New listing(Minor Submission) | EPOPROSTENOLInjection 500 microgram Injection 1.5 mg Flolan®GlaxoSmithKline Australia Pty Ltd | Pulmonary arterial hypertension | To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing of a new pH 12 diluent and delisting of the infusion administration set.  |
| Change to listing(Major Submission) | ERIBULINSolution for I.V. injection containing eribulin mesilate 1 mg in 2 mLHalaven®Eisai Australia Pty Ltd | Soft tissue sarcoma | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of unresectable or metastatic liposarcoma following chemotherapy. |
| New listing(Minor Submission) | FLUTICASONE with SALMETEROLPowder for inhalation containing fluticasone propionate 500 micrograms with salmeterol (as xinafoate) 50 micrograms per doseAirflusal Forspiro 500/50Sandoz Pty Ltd | Asthma and chronic obstructive pulmonary disease (COPD) | To request the Restricted Benefit listing for asthma and chronic obstructive pulmonary disease, with an age restriction of 18 years and older. |
| New listing(Minor Submission) | FOSAPREPITANTPowder for I.V. infusion 150 mgEmend® IVMerck Sharp & Dohme (Australia) Pty Ltd | Nausea and vomiting | Resubmission to request a General Schedule and Section 100 (Efficient Funding of Chemotherapy - Related Benefits) Authority Required (STREAMLINED) listing of an intravenous formulation of fosaprepitant for the management of nausea and vomiting associated with cytotoxic chemotherapy. |
| New listing(Minor Submission) | GLYCOMACROPEPTIDE and ESSENTIAL AMINO ACIDS with VITAMINS and MINERALSSachet containing oral powder 35 gPKU Sphere®Vitaflo Australia Pty Ltd | Phenylketonuria | To request a Restricted Benefit listing for the dietary management of phenylketonuria. |
| New listing(Minor Submission) | GLYCOMACROPEPTIDE and ESSENTIAL AMINO ACIDSSachets containing oral powder 20 gPKU Restore®Cortex Health Pty Ltd | Phenylketonuria | To request a Restricted Benefit for the dietary management of phenylketonuria. |
| New listing(Minor Submission) | GONADOTROPHINPowder for injection, 600 I.UPowder for injection, 1200 I.UMenopur®Ferring Pharmaceuticals Pty Ltd   | Anovulatory infertility | Resubmission to request a restricted benefit listing for anovulatory infertility. |
| Change to listing(Minor Submission) | GOSERELINImplant, 3.6 mg Implant 10.8 mgZoladex® ImplantMedical Oncology Group of Australia | Chemotherapy-induced menopause | To request a Restricted Benefit listing for the prevention of chemotherapy-induced menopause in breast cancer. |
| New listing(Minor Submission) | HIGH FAT FORMULA with VITAMINS, MINERALS and TRACE ELEMENTS and LOW IN PROTEIN and CARBOHYDRATEOral semi-solid 100 gKeyo®Vitaflo Australia Pty Ltd | Dietary management of conditions requiring a ketogenic diet | To request a Restricted Benefit listing as a dietary supplement for patients requiring a ketogenic diet. |
| New listing(Major Submission) | IBRUTINIBCapsule 140 mgImbruvica®Janssen-Cilag Pty Ltd | Relapsed or refractory mantle cell lymphoma | To request an Authority Required listing for the treatment of relapsed or refractory mantle cell lymphoma. |
| Change to listing(Major Submission) | ICATIBANTInjection 30 mg (as acetate) in 3 mL single use pre-filled syringeFirazyr®Shire Australia Pty Ltd | Hereditary angioedema | To request assessment of the cost-effectiveness of icatibant in the context of the current Australian Society of Clinical Immunology and Allergy (ASCIA) treatment algorithm and June 2016 DUSC review. |
| New listing(Major Submission) | INFLIXIMABPowder for I.V. infusion 100 mgRenflexis®Merck Sharp & Dohme (Australia) Pty Ltd | Same as currently PBS subsidised indications for infliximab | To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing of a biosimilar infliximab for all indications currently PBS subsidised for infliximab. |
| New listing(Major Submission) | IRINOTECAN (NANOLIPOSOMAL) Injection concentrate for I.V. infusion 43 mg in 10 mLOnivyde®Baxalta Australia Pty Ltd | Metastatic pancreatic cancer  | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for use in combination with 5-fluorouracil and folinic acid, for the treatment of patients with metastatic pancreatic cancer previously treated with a gemcitabine based regimen. |
| Change to listing(Major Submission) | IVACAFTORSachet containing granules 50 mgSachet containing granules 75 mgKalydeco®Vertex Pharmaceuticals (Australia) Pty Ltd | Cystic fibrosis  | To request a Section 100 (Highly Specialised Drugs Program) listing of a new form of ivacaftor; and an extension to current ivacaftor listing to include patients aged 2-5 years who have a G551D or other gating (class III) mutation in the CFTR gene. |
| Change to listing(Major Submission) | LANREOTIDEInjection 60 mg (as acetate) in single dose pre-filled syringe Injection 90 mg (as acetate) in single dose pre-filled syringe Injection 120 mg (as acetate) in single dose pre-filled syringeSomatuline® Autogel®Ipsen Pty Ltd | Gastroentero-pancreatic neuroendocrine tumours (GEP-NETs) | Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of non-functional GEP-NETs in adult patients with un-resectable locally advanced or metastatic disease. |
| Change to listing(Major Submission)WITHDRAWN | LEDIPASVIR with SOFOSBUVIRTablet containing 90 mg ledipasvir with 400 mg sofosbuvirHarvoni®Gilead Sciences Pty Ltd | Chronic hepatitis C virus (HCV) infection | To request an extension to the General Schedule and Section 100 (Highly Specialised Drugs Program) Authority Required listings for ledipasvir with sofosbuvir, for use in combination with ribavirin, for the treatment of patients with HCV genotypes 1 to 6 with decompensated cirrhosis and treatment-naïve patients with HCV genotype 3 with and without cirrhosis. |
| Change to listing(Minor Submission) | LEVODOPA with CARBIDOPAIntestinal gel containing levodopa 20 mg with carbidopa (as monohydrate) 5 mg in 1 mLDuodopa®Abbvie Pty Ltd | Parkinson disease | To request a change in the Note section of the current Authority Required (STREAMLINED) restriction. |
| New listing(Minor Submission) | LUMACAFTOR with IVACAFTORTablet containing lumacaftor 200 mg with ivacaftor 125 mgOrkambi®Vertex Pharmaceuticals (Australia) Pty Ltd  | Cystic fibrosis  | Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of cystic fibrosis in patients aged 12 years and older who are homozygous for the F508del mutation in the CFTR gene. |
| Change to listing(Minor Submission) | NADROPARIN Injection containing nadroparin calcium (1,900 I.U. anti-Xa) in 0.2 mL(2,850 I.U. anti-Xa) in 0.3 mL(3800 IU anti-Xa) in 0.4 mL (5700 IU anti-Xa) in 0.6 mL (7600 IU anti-Xa) in 0.8 mL (9500 IU anti-Xa) in 1 mL (11400 IU anti-Xa) in 0.6 mL(15200 IU anti-Xa) in 0.8 mL(19000 IU anti-Xa) in 1 mL prefilled syringeFraxiparine® and Fraxiparine Forte®Aspen Pharmacare Australia Pty Ltd | Deep Vein Thrombosis (DVT) prophylaxis/treatmentHaemodialysis | To request an increase in maximum quantities for all strengths of the listed formulations. |
| Change to listing(Major Submission) | NETUPITANT with PALONOSETRONCapsule containing netupitant 300 mg with palonosetron 500 microgram (as hydrochloride)Akynzeo®Mundipharma Pty Ltd | Nausea and vomiting associated with emetogenic cancer chemotherapy | Resubmission to request General Schedule and Section 100 (Efficient Funding of Chemotherapy – Related Benefits) Authority Required (STREAMLINED) listings for the treatment of nausea and vomiting associated with moderately emetogenic cytotoxic chemotherapy. |
| Change to listing(Minor Submission)WITHDRAWN | NILOTINIBCapsule 150 mg (as hydrochloride monohydrate)Capsule 200 mg (as hydrochloride monohydrate)Tasigna®Novartis Pharmaceuticals Australia Pty Ltd | Chronic myeloid leukaemia (CML) | To request the current Authority Required (IN-WRITING) listings for CML be changed to Authority Required (TELEPHONE). |
| New listing(Major Submission) | NINTEDANIBCapsule 100 mgCapsule 150 mgOfev®Boehringer Ingelheim Pty Ltd | Idiopathic pulmonary fibrosis (IPF) | Resubmission to request an Authority Required listing for use in patients with IPF. |
| Change to listing(Major Submission) | NIVOLUMABInjection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mLOpdivo®Bristol-Myers Squibb Australia Pty Ltd | Squamous non-small cell lung cancer (NSCLC) | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of locally advanced or metastatic squamous NSCLC with progression on or after prior chemotherapy. |
| Change to listing(Major Submission) | NIVOLUMABInjection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mLOpdivo®Bristol-Myers Squibb Australia Pty Ltd | Non-squamous non-small cell lung cancer (NSCLC) | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of locally advanced or metastatic non-squamous NSCLC with progression on or after prior chemotherapy. |
| New listing(Minor Submission) | NIVOLUMABInjection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mLOpdivo®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 clear cell variant renal cell carcinoma. |
| New listing(Major Submission) | OBINUTUZUMABSolution for I.V. infusion 1000 mg in 40 mLGazyva®Roche Products Pty Ltd | Follicular lymphoma | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing as re-induction treatment and maintenance therapy in patients with rituximab-refractory follicular lymphoma. |
| Change to listing(Minor Submission) | OMALIZUMABInjection 150 mg in 1 mLXolair®Novartis Pharmaceuticals Australia Pty Ltd | Severe chronic idiopathic urticaria | Resubmission to request a re-assessment of the recommended equi-effective dose of omalizumab compared with cyclosporin. |
| New listing(Minor Submission) | OXYCODONE with NALOXONETablet (controlled release) containing oxycodone hydrochloride 80 mg with naloxone hydrochloride 40 mgTablet (controlled release) containing oxycodone hydrochloride 60 mg with naloxone hydrochloride 30 mgTargin®Mundipharma Pty Ltd | Chronic severe disabling pain | To request an Authority Required listing for two additional strengths of oxycodone with naloxone for the treatment of chronic disabling pain unresponsive to non-opioid analgesics. |
| Change to listing(Minor Submission)WITHDRAWN | OXYCODONE with NALOXONETablet (controlled release) containing oxycodone (as hydrochloride) 2.5 mg with naloxone (as hydrochloride)1.25 mgTablet (controlled release) containing oxycodone (as hydrochloride) 5 mg with naloxone (as hydrochloride)2.5 mg,Tablet (controlled release) containing oxycodone (as hydrochloride) 10 mg with naloxone (as hydrochloride) 5 mgTablet (controlled release) containing oxycodone (as hydrochloride) 15 mg with naloxone (as hydrochloride) 7.5 mgTablet (controlled release) containing oxycodone (as hydrochloride) 20 mg with naloxone (as hydrochloride)10 mgTablet (controlled release) containing oxycodone (as hydrochloride) 30 with naloxone (as hydrochloride) 15 mgTablet (controlled release)Targin®Mundipharma Pty Ltd | Chronic severe disabling pain | To request the addition of a note to its current Restricted Benefit listing. |
| New listing(Major Submission) | PALIPERIDONEI.M. injection (modified release) 175 mg (as palmitate) in pre-filled syringeI.M. injection (modified release) 263 mg (as palmitate) in pre-filled syringeI.M. injection (modified release) 350 mg (as palmitate) in pre-filled syringeI.M. injection (modified release) 525 mg (as palmitate) in pre-filled syringeInvega® Trinza™Janssen-Cilag Pty Ltd | Schizophrenia | To request an Authority Required (STREAMLINED) listing for the treatment of patients with schizophrenia who have been adequately stabilised with paliperidone modified release injection. |
| New listing(Major Submission) | PARITAPREVIR with RITONAVIR with OMBITASVIRTablet containing 75 mg paritaprevir with 50 mg ritonavir with 12.5 mg ombitasvirTechnivie®AbbVie Pty Ltd | Chronic hepatitis C virus (HCV) infection | To request General Schedule and Section 100 (Highly Specialised Drugs Program) Authority Required listings for paritaprevir with ritonavir with ombitasvir, in combination with ribavirin, for the treatment of patients with genotype 4 chronic HCV infection. |
| New listing(Major Submission) | PEGVISOMANTPowder for injection 10 mgPowder for injection 15 mgPowder for injection 20 mgSomavert®Pfizer Australia Pty Ltd | Acromegaly | To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of acromegaly in patients who have had inadequate response to surgery and/or radiation and/or other medical therapies. |
| New listing(Minor Submission) | PEMBROLIZUMABPowder for injection 100 mgKeytruda®Merck Sharp & Dohme (Australia) Pty Ltd | Melanoma | To request a Section 100 (Efficient funding of Chemotherapy) Authority Required (STREAMLINED) listing of an additional strength of pembrolizumab for unresectable stage III or stage IV malignant melanoma |
| Change to listing(Major Submission) | PEMBROLIZUMABPowder for injection 50 mgKeytruda®Merck Sharp and Dohme (Australia) Pty Ltd | Non-small cell lung cancer (NSCLC) | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of PD-L1 positive NSCLC in patients refractory to platinum based chemotherapy. |
| Change to listing(Major Submission) | PEMBROLIZUMABPowder for injection 50 mgKeytruda®Merck Sharp & Dohme (Australia) Pty Ltd | Melanoma | Resubmission to seek PBAC reconsideration of the cost-effectiveness of pembrolizumab for the treatment of unresectable stage III or stage IV metastatic melanoma. |
| New listing(Major Submission) | PIRFENIDONE Capsule 267 mgEsbriet®Roche Products Pty Ltd | Idiopathic pulmonary fibrosis (IPF) | Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of IPF. |
| New listing(Major Submission) | ROMIDEPSINPowder for I.V. infusion 10 mgIstodax®Rare Cancers Australia | Relapsed or refractory peripheral T-cell lymphoma | To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of relapsed or chemotherapy refractory peripheral T-cell lymphoma. |
| Change to listing(Minor Submission) | SALBUTAMOLNebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 20Nebuliser solution 5 mg (as sulfate) in 2.5 mL single dose units, 20Ventolin Nebules®GlaxoSmithKline Australia Pty Ltd | Asthma | To request a change to the pack size. |
| New listing(Major Submission) | SOFOSBUVIR with VELPATASVIRTablet containing 400 mg sofosbuvir with 100 mg velpatasvirEpclusa®Gilead Sciences Pty Ltd | Chronic hepatitis C virus (HCV) infection | To request General Schedule and Section 100 (Highly Specialised Drugs Program) Authority Required listings for the treatment of chronic HCV infection, regardless of genotype. For patients with decompensated liver disease, the requested listing is in combination with ribavirin. |
| Change to listing(Minor Submission) | SOMATROPINInjection 6 mg (18 i.u.) in 1.03 mL 12 mg (36 i.u.) in 1.5 mL 20 mg (60 i.u.) in 2.5 mLcartridge (with preservative)Saizen®Merck Serono Australia Pty Ltd  | Severe growth hormone deficiency | To request an Authority Required listing for the treatment of growth disturbance (growth retardation) in pre-pubertal children due to chronic renal insufficiency (CRI). |
| Change to listing(Major Submission) | SOMATROPINAll forms and strengthsAll brandsEndocrine Society of Australia;Australian Paediatric Endocrine Group | Severe growth hormone deficiency | Resubmission to request a Section 100 (Growth Hormone) Authority Required listing for the treatment of adults with severe growth hormone deficiency and substantially impaired quality of life at baseline. |
| Change to listing(Minor Submission) | TERIFLUNOMIDE Tablet 14 mgAubagio®Sanofi-aventis Australia Pty Ltd | Multiple sclerosis | To request the current Authority Required listing be changed to Authority Required (STREAMLINED). |
| Change to listing(Minor Submission) | TIOTROPIUM with OLODATEROLSolution for oral inhalation containing tiotropium 2.5 micrograms (as bromide monohydrate) with olodaterol 2.5 micrograms (as hydrochloride) per dose, 60 dosesSpiolto® Respimat®Boehringer Ingelheim Pty Ltd | Chronic obstructive pulmonary disease (COPD) | To request a change to the current Authority Required (STREAMLINED) listing for tiotropium with olodaterol to include patients who have persistent COPD symptoms despite regular monotherapy with a long-acting muscarinic antagonist or a long-acting beta-2 agonist. |
| Change to recommended listing(Minor Submission)WITHDRAWN | TOCILIZUMAB Injection 162 mg in 0.9 mLActemra®Roche Products Pty Ltd | Rheumatoid arthritis | Resubmission to request a revision of the March 2016 PBAC recommendation. |
| New listing(Major Submission) | TOLVAPTANTablet 15 mgTablet 30 mgPack containing 28 tablets 15 mg and 28 tablets 45 mgPack containing 28 tablets 30 mg and 28 tablets 60 mgPack containing 28 tablets 30 mg and 28 tablets 90 mgJinarc®Otsuka Australia Pharmaceutical Pty Ltd | Autosomal dominant polycystic kidney disease (ADPKD) | To request an Authority Required listing for the treatment of ADPKD. |
| New listing(Major Submission) | TRIFLURIDINE with TIPIRACILTablet containing 15 mg trifluridine with 6.14 mg tipiracil Tablet containing 20 mg trifluridine with 8.19 mg tipiracilLonsurf®Servier Laboratories (Australia) Pty Ltd | Metastatic colorectal cancer | To request an Authority Required (STREAMLINED) listing for the treatment of metastatic colorectal cancer. |
| New listing(Minor Submission) | TRIGLYCERIDES MEDIUM CHAIN and LONG CHAIN with GLUCOSE POLYMER Sachet containing oral powder 21 gSachet containing oral powder 31 gSachet containing oral powder 42 gSachet containing oral powder 52 gSOS10®, SOS15®, SOS20®, SOS25®Vitaflo Australia Pty Ltd | Dietary management of proven inborn errors of protein or fat metabolism | To request a Restricted Benefit listing for proven inborn errors of protein or fat metabolism. |
| New listing(Minor Submission) | TRIGLYCERIDES MEDIUM CHAIN FORMULAOral liquid solution, 500mLNutrini Peptisorb Energy Nutricia Australia Pty Ltd | Dietary management of conditions requiring a source of medium chain triglycerides | To request a Restricted Benefit listing for dietary management of conditions requiring a source of medium chain triglycerides. |
| Change to listing(Minor Submission) | VARENICLINEBox containing 11 tablets 0.5 mg (as tartrate) and 14 tablets 1 mg (as tartrate) in the first pack and 28 tablets 1 mg (as tartrate) in the second packTablet 1 mg (as tartrate)Champix®Pfizer Australia Pty Ltd | Nicotine dependence | To request the current Authority Required listing be changed to Authority Required (STREAMLINED). |
| Change to recommended listing(Minor Submission) | VISMODEGIBCapsule 150 mgErivedge®Roche Products Pty Ltd | Metastatic or locally advanced basal cell carcinoma (BCC) | Resubmission to supply new clinical information in relation to the March 2016 PBAC recommendation of vismodegib for the treatment of metastatic or locally advanced BCC. |
| Change to listing(Minor Submission) | VITAMIN, MINERAL, AND TRACE ELEMENTS with CARBOHYDRATESachet 6 gFruitivits®Vitaflo Australia Pty Ltd | Dietary management of conditions requiring a highly restrictive therapeutic diet | To request a change to the restriction to include children aged 1 year or older. |
| New listing(Major Submission) | VORINOSTATCapsule 100 mgZolinza® Rare Cancers Australia | Relapsed or refractory cutaneous T-cell lymphoma | Resubmission to request an Authority Required listing for the treatment of relapsed or chemotherapy refractory cutaneous T-cell lymphoma. |
| New listing(Minor Submission) | WARFARINTablet containing warfarin sodium, 1 mgTablet containing warfarin sodium, 2 mgTablet containing warfarin sodium, 5 mgWarfarin APOTEX®Apotex Pty Ltd | Unrestricted | To request the listing of a new brand of warfarin (Warfarin APOTEX®) with an ‘a-flag’ to a currently listed brand of warfarin (Coumadin®). |
| Sub-committee report(DUSC Analysis) | PosaconazoleVoriconazoleFluconazoleItraconazoleTerbinafineGriseofulvinKetoconazole (all current and previously listed brands including generic versions) | Antifungals | To assess the use of PBS listed antifungal medicines, including the comparison of the predicted and actual use of voriconazole since the addition of an Authority Required listing for prophylaxis of fungal infections in certain high risk patients. |
| Sub-committee report(DUSC Analysis) | QuetiapineAmisulprideAripiprazoleAsenapineClozapineLurasidoneOlanzapinePaliperidoneZiprasidone RisperidoneLithium(all current and previously listed brands including generic versions) | Antipsychotics | To assess the use of PBS listed antipsychotic medicines, including the comparison of the predicted and actual use of 25 mg quetiapine after the restriction was altered to remove repeats from PBS prescriptions.  |
| Sub-committee report(DUSC Analysis) | Mifepristone and misoprostolMS 2 Step® | Termination of intra-uterine pregnancies  | To compare the predicted and actual use of PBS listed mifepristone and misoprostol. |
| Sub-committee report(DUSC Analysis) | DenosumabAlendronateClodronateRisedronateZoledronic acidCalcitriol RaloxifeneTeriparatideAlendronate + Colecalciferol Alendronate & Colecalciferol + CalciumRisedronate & CalciumRisedronate & Calcium + Colecalciferol(all current and previously listed brands including generic versions) | Osteoporosis | To assess the use of the medicines PBS listed to treat osteoporosis, including the comparison of the predicted and actual use of denosumab. |
| Sub-committee report(DUSC Analysis) | RifaximinXifaxan® | Hepatic encephalopathy | To compare the predicted and actual use of rifaximin. |
| Sub-committee report(DUSC Analysis) | TestosteroneTestosterone enanthateTestosterone undecanoate(all current and previously listed brands including generic versions) | Androgen deficiency | To examine the use of PBS listed testosterone to assess the impact of the change in restriction that occurred 1 April 2015. |