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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  (Minor Submission) | AMINO ACID FORMULA with FAT, CARBOHYDRATE, VITAMINS, MINERALS and TRACE ELEMENTS without PHENYLALANINE  Bottles containing oral powder 34 g, 30  PKU EASY® SHAKE & GO  AMINO ACID FORMULA with FAT,  CARBOHYDRATE without PHENYLALANINE  Tablet: 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 ACID  Oral 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) | ADALIMUMAB  Injection 40 mg in 0.8 mL pre-filled pen Injection 40 mg in 0.8 mL pre-filled syringe  Humira®  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) | APOMORPHINE  Injection containing apomorphine (as hydrochloride) 100 mg in 20 mL  Apomine®  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) | APREMILAST  Tablet 30 mg Pack containing 4 tablets 10 mg, 4 tablets 20 mg and 19 tablets 30 mg  Otezla®  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) | BLINATUMOMAB  Injection 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 VEDOTIN  Powder for I.V. infusion 50 mg  Adcetris®  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 VEDOTIN  Powder for I.V. infusion 50 mg  Adcetris®  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 BETAMETHASONE  Foam containing calcipotriol 50 micrograms with betamethasone 500 micrograms (as dipropionate) per g, 60 g  Enstilar®  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) | CARFILZOMIB  Powder for I.V. infusion 30 mg Powder for I.V. infusion 60 mg  Kyprolis®  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) | CERITINIB  Capsule 150 mg  Zykadia®  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) | CETUXIMAB  Injection 100 mg in 20 mL  Injection 500 mg in 100 mL  Erbitux®  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 | EDOXABAN  Tablet 30 mg Tablet 60 mg  Lixiana®  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 | EDOXABAN  Tablet 30 mg Tablet 60 mg  Lixiana®  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) | EPOPROSTENOL  Injection 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) | ERIBULIN  Solution for I.V. injection containing eribulin mesilate 1 mg in 2 mL  Halaven®  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 SALMETEROL  Powder for inhalation containing fluticasone propionate 500 micrograms with salmeterol (as xinafoate) 50 micrograms per dose  Airflusal Forspiro 500/50  Sandoz 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) | FOSAPREPITANT  Powder for I.V. infusion 150 mg  Emend® IV  Merck 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 MINERALS  Sachet containing oral powder 35 g  PKU 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 ACIDS  Sachets containing oral powder 20 g  PKU Restore®  Cortex Health Pty Ltd | Phenylketonuria | To request a Restricted Benefit for the dietary management of phenylketonuria. |
| New listing  (Minor Submission) | GONADOTROPHIN  Powder for injection, 600 I.U Powder for injection, 1200 I.U  Menopur®  Ferring Pharmaceuticals Pty Ltd | Anovulatory infertility | Resubmission to request a restricted benefit listing for anovulatory infertility. |
| Change to listing  (Minor Submission) | GOSERELIN  Implant, 3.6 mg Implant 10.8 mg  Zoladex® Implant  Medical 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 CARBOHYDRATE  Oral semi-solid 100 g  Keyo®  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) | IBRUTINIB  Capsule 140 mg  Imbruvica®  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) | ICATIBANT  Injection 30 mg (as acetate) in 3 mL single use pre-filled syringe  Firazyr®  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) | INFLIXIMAB  Powder for I.V. infusion 100 mg  Renflexis®  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 mL  Onivyde®  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) | IVACAFTOR  Sachet containing granules 50 mg Sachet containing granules 75 mg  Kalydeco®  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) | LANREOTIDE  Injection 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 syringe  Somatuline® 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 SOFOSBUVIR  Tablet containing 90 mg ledipasvir with 400 mg sofosbuvir  Harvoni®  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 CARBIDOPA  Intestinal gel containing levodopa 20 mg with carbidopa (as monohydrate) 5 mg in 1 mL  Duodopa®  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 IVACAFTOR  Tablet containing lumacaftor 200 mg with ivacaftor 125 mg  Orkambi®  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 syringe  Fraxiparine® and Fraxiparine Forte®  Aspen Pharmacare Australia Pty Ltd | Deep Vein Thrombosis (DVT) prophylaxis/treatment Haemodialysis | To request an increase in maximum quantities for all strengths of the listed formulations. |
| Change to listing  (Major Submission) | NETUPITANT with PALONOSETRON  Capsule 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 | NILOTINIB  Capsule 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) | NINTEDANIB  Capsule 100 mg Capsule 150 mg  Ofev®  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) | 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 | 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) | 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 | 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) | 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 clear cell variant renal cell carcinoma. |
| New listing  (Major Submission) | OBINUTUZUMAB  Solution for I.V. infusion 1000 mg in 40 mL  Gazyva®  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) | OMALIZUMAB  Injection 150 mg in 1 mL  Xolair®  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 NALOXONE  Tablet (controlled release) containing oxycodone hydrochloride 80 mg with naloxone hydrochloride 40 mg Tablet (controlled release) containing oxycodone hydrochloride 60 mg with naloxone hydrochloride 30 mg  Targin®  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 NALOXONE  Tablet (controlled release) containing oxycodone (as hydrochloride) 2.5 mg with naloxone (as hydrochloride)1.25 mg  Tablet (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 mg  Tablet (controlled release) containing oxycodone (as hydrochloride) 15 mg with naloxone (as hydrochloride) 7.5 mg  Tablet (controlled release) containing oxycodone (as hydrochloride) 20 mg with naloxone (as hydrochloride)10 mg  Tablet (controlled release) containing oxycodone (as hydrochloride) 30 with naloxone (as hydrochloride) 15 mg  Tablet (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) | PALIPERIDONE  I.M. injection (modified release) 175 mg (as palmitate) in pre-filled syringe I.M. injection (modified release) 263 mg (as palmitate) in pre-filled syringe I.M. injection (modified release) 350 mg (as palmitate) in pre-filled syringe I.M. injection (modified release) 525 mg (as palmitate) in pre-filled syringe  Invega® 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 OMBITASVIR  Tablet containing 75 mg paritaprevir with 50 mg ritonavir with 12.5 mg ombitasvir  Technivie®  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) | PEGVISOMANT  Powder for injection 10 mg  Powder for injection 15 mg  Powder for injection 20 mg  Somavert®  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) | PEMBROLIZUMAB  Powder for injection 100 mg  Keytruda®  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) | PEMBROLIZUMAB  Powder for injection 50 mg  Keytruda®  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) | PEMBROLIZUMAB  Powder for injection 50 mg  Keytruda®  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 mg  Esbriet®  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) | ROMIDEPSIN  Powder for I.V. infusion 10 mg  Istodax®  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) | SALBUTAMOL  Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 20  Nebuliser solution 5 mg (as sulfate) in 2.5 mL single dose units, 20  Ventolin Nebules®  GlaxoSmithKline Australia Pty Ltd | Asthma | To request a change to the pack size. |
| New listing  (Major Submission) | SOFOSBUVIR with VELPATASVIR  Tablet containing 400 mg sofosbuvir with 100 mg velpatasvir  Epclusa®  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) | SOMATROPIN  Injection  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 mL cartridge (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) | SOMATROPIN  All forms and strengths  All brands  Endocrine 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 mg  Aubagio®  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 OLODATEROL  Solution for oral inhalation containing tiotropium 2.5 micrograms (as bromide monohydrate) with olodaterol 2.5 micrograms (as hydrochloride) per dose, 60 doses  Spiolto® 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 mL  Actemra®  Roche Products Pty Ltd | Rheumatoid arthritis | Resubmission to request a revision of the March 2016 PBAC recommendation. |
| 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 (ADPKD) | To request an Authority Required listing for the treatment of ADPKD. |
| New listing  (Major Submission) | TRIFLURIDINE with TIPIRACIL  Tablet containing 15 mg trifluridine with 6.14 mg tipiracil  Tablet containing 20 mg trifluridine with 8.19 mg tipiracil  Lonsurf®  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 g Sachet containing oral powder 31 g Sachet containing oral powder 42 g Sachet containing oral powder 52 g  SOS10®, 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 FORMULA  Oral liquid solution, 500mL  Nutrini 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) | VARENICLINE  Box 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 pack Tablet 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) | VISMODEGIB  Capsule 150 mg  Erivedge®  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 CARBOHYDRATE  Sachet 6 g  Fruitivits®  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) | VORINOSTAT  Capsule 100 mg  Zolinza®   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) | WARFARIN  Tablet containing warfarin sodium, 1 mg Tablet containing warfarin sodium, 2 mg Tablet containing warfarin sodium, 5 mg  Warfarin 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) | Posaconazole Voriconazole Fluconazole Itraconazole Terbinafine Griseofulvin Ketoconazole   (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) | Quetiapine Amisulpride Aripiprazole Asenapine Clozapine Lurasidone Olanzapine Paliperidone Ziprasidone  Risperidone Lithium  (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 misoprostol  MS 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) | Denosumab Alendronate Clodronate Risedronate Zoledronic acid Calcitriol  Raloxifene Teriparatide Alendronate + Colecalciferol  Alendronate & Colecalciferol + Calcium Risedronate & Calcium Risedronate & 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) | Rifaximin  Xifaxan® | Hepatic encephalopathy | To compare the predicted and actual use of rifaximin. |
| Sub-committee report  (DUSC Analysis) | Testosterone Testosterone enanthate Testosterone 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. |