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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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| New listing(Major Submission) | ABEMACICLIBTablet 50mgTablet 100mgTablet 150mgVerzenio®Eli Lilly Australia Pty Ltd | Advanced breast cancer | To request an Authority Required listing for the treatment of non-premenopausal patients with hormone receptor positive (HR+), human epidermal growth factor receptor-2 negative (HER2-) locally advanced or metastatic breast cancer. |
| Change to listing(Minor Submission) | ALECTINIBCapsule 150 mgAlecensa®Roche Products Pty Ltd | Non-small cell lung cancer (NSCLC) | To request a change in the authority level of the current listing from Authority Required (Telephone) to Authority Required (STREAMLINED) and an increase in the maximum number of repeats from 1 to 5. |
| New listing(Major Submission) | ALIROCUMABInjection 75 mg in 1 mL single dose pre-filled penInjection 150 mg in 1 mL single dose pre-filled penPraluent® Sanofi-Aventis Australia Pty Ltd | Hypercholesterolaemia  | Resubmission to request an Authority Required listing for the treatment of patients:* with familial heterozygous hypercholesterolaemia; or
* with hypercholesterolaemia with previous acute coronary syndrome and concomitant diabetes.
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| Change to listing(Major Submission) | ATEZOLIZUMAB and BEVACIZUMABAtezolizumab:Solution concentrate for I.V. infusion 1200 mg in 20 mLBevacizumab:Solution for I.V. infusion 100 mg in 4 mLSolution for I.V. infusion 400 mg in 16 mLTecentriq® and Avastin®Roche Products Pty Ltd  | Non-small cell lung cancer (NSCLC) | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of metastatic NSCLC in combination with platinum-doublet chemotherapy in:* epidermal growth factor receptor (EGFR) wild type/ anaplastic lymphoma kinase (ALK) negative patients; or
* EGFR/ALK mutation positive patients who have progressed on or after prior treatment with a tyrosine kinase inhibitor (TKI).
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| New listing(Minor Submission) | BENZATHINE BENZYLPENICILLINInjection 517 mg in 1.17 mL single use pre-filled syringeBicillin L-A®Pfizer Australia Pty Ltd | Treatment of infections  | To request an unrestricted benefit listing of a new strength of benzathine benzylpenicillin injection. |
| New listing(Minor Submission) | BEVACIZUMABSolution for I.V. infusion 100 mg in 4 mLSolution for I.V. infusion 400 mg in 16 mLAvastin®Roche Products Pty Ltd | Glioblastoma multiforme/Grade IV glioma (GBM) | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy), Authority Required (STREAMLINED) listing for the treatment of relapsed or refractory GBM. |
| Change to listing(Major Submission) | BLINATUMOMABPowder for I.V. infusion 38.5 microgramsBlincyto®Amgen Australia Pty Ltd | Acute lymphoblastic leukaemia (ALL) | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) listing for the treatment of patients with B-cell precursor ALL in patients in haematological complete remission with minimal residual disease following chemotherapy. |
| Change to listing(Minor Submission) | BOTULINUM TOXIN TYPE ALyophilised powder for injection 100 unitsBotox® Allergan Australia Pty Ltd | Focal spasticity of the lower limb | Resubmission to request an extension to the current Section 100 (Botulinum Toxin Program) listing to include the treatment of lower limb focal spasticity in adults following stroke, who meet certain conditions. |
| New listing(Minor Submission) | BUDESONIDECapsule (modified release) 3 mgBudenofalk®Orphan Australia Pty Ltd | Crohn disease | To request an Authority Required (STREAMLINED) listing for the treatment of patients with mild to moderate Crohn disease. |
| New listing(Minor Submission) | BUDESONIDECapsule (modified release) 3 mgEntocort®Emerge Health Pty Ltd | Mild to moderate Crohn disease | Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with mild to moderate Crohn disease. |
| New listing(Major Submission) | BUPRENORPHINEInjection (modified release) 100 mg in 0.5 mL pre-filled syringeInjection (modified release) 300 mg in 1.5 mL pre-filled syringeSublocade®Indivior Pty Ltd | Opiate dependence | To request a Section 100 (Opiate Dependence Treatment Program) listing for the treatment of patients with opioid use disorder.  |
| New listing(Minor Submission) | BUPRENORPHINEInjection 8 mg in 0.16 mL pre-filled syringe Injection 16 mg in 0.32 mL pre-filled syringeInjection 24 mg in 0.48 mL pre-filled syringeInjection 32 mg in 0.64 mL pre-filled syringeInjection 64 mg in 0.18 mL pre-filled syringeInjection 96 mg in 0.27 mL pre-filled syringeInjection 128 mg in 0.36 mL pre-filled syringeBuvidal®Camurus AB | Opiate dependence | Resubmission to request a Section 100 (Opiate Dependence Treatment Program) listing for the treatment of patients with opiate dependence.  |
| Change to listing(Major Submission) | CABOZANTINIBTablet 20 mgTablet 40 mgTablet 60 mgCabometyx®Ipsen Pty Ltd  | Renal cell carcinoma (RCC) | To request an extension to the current listing for the treatment of Stage IV clear cell variant RCC to include previously untreated patients.  |
| New listing(Minor Submission) | CALCIUMTablet, chewable, 500 mg (as carbonate)Cal-500®Petrus Pharmaceuticals Pty Ltd | Hyperphosphataemia | To request an Authority Required (STREAMLINED) listing of a new larger pack size of calcium for the treatment of hyperphosphataemia. |
| Change to listing(Major Submission) | CERTOLIZUMAB PEGOLInjection 200mg in 1 mL pre-syringe penSolution for injection 200 mg in 1 mL pre-filled penCimzia®UCB Australia Pty Ltd | Severe chronic plaque psoriasis  | To request an Authority Required listing for the treatment of patients with severe chronic plaque psoriasis.  |
| Change to listing(Minor Submission) | CLOSTRIDIUM BOTULINUM TYPE A TOXIN – HAEMAGGLUTININ C COMPLEX Lyophilised powder for I.M. injection 300 unitsLyophilised powder for I.M. injection 500 unitsDysport®Ipsen Pty Ltd | Spasticity of the upper limb  | Resubmission to extend the current Section 100 (Botulinum Toxin Program) listing to include treatment of patients with moderate to severe spasticity of the upper limb following an acute event, and to remove the current restriction on the number of treatment periods in a lifetime. |
| Change to listing(Major Submission) | DABRAFENIB and TRAMETINIBDabrafenib:Capsule 50 mgCapsule 75 mgTrametinib:Tablet 500 microgramTablet 2 mgTafinlar® andMekinist®Novartis Pharmaceuticals Australia Pty ltd | Melanoma | 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.  |
| New listing(Major Submission) | DARATUMUMABSolution concentrate for I.V infusion 100mg in 5 mLSolution concentrate for I.V infusion 400mg in 20 mLDarzalex®Janssen-Cilag Pty Ltd | Multiple myeloma | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of multiple myeloma: * in combination with bortezomib and dexamethasone for the treatment of relapsed or refractory multiple myeloma in patients who have progressive disease after at least one prior therapy; or
* as monotherapy for highly treatment experienced and refractory patients
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| Change of listing(Major Submission) | DARBEPOETIN ALFA Injection 200 micrograms in 0.4 mL pre-filled syringeInjection 300 micrograms in 0.6 mL pre-filled syringeInjection 500 micrograms in 1 mL pre-filled syringeAranesp®Amgen Australia Pty Ltd | Chemotherapy-induced anaemia  | Resubmission to request a Section 100 (Highly Specialised Drug) Authority Required listing for chemotherapy-induced anaemia.  |
| Change to listing(Minor Submission) | DASATINIBTablet 20mgTablet 50mgTablet 70mgTablet 100mgSprycel®Bristol-Myers Squibb Australia Pty Ltd | Acute lymphoblastic leukaemia (ALL) | To request an extension to the current Authority Required (in writing) listing for the treatment of Philadelphia chromosome positive (Ph+) ALL to include newly diagnosed patients.  |
| Change to listing(Minor Submission) | ENOXAPARINInjection containing enoxaparin sodium 20 mg (2,000 I.U. anti-Xa) in 0.2 mL pre-filled syringeInjection containing enoxaparin sodium 40 mg (4,000 I.U. anti-Xa) in 0.4 mL pre-filled syringeClexane®Sanofi-Aventis Australia Pty Ltd | Venous thromboembolism (VTE) prophylaxis  | To request an increase in the maximum number of repeats from 0 to 1 for the unrestricted listing of enoxaparin.  |
| New listing(Major Submission) | ERENUMABInjection 70 mg in 1 mL single dose pre-filled penAimovig®Novartis Pharmaceuticals Australia Pty Ltd | Chronic migraine  | Resubmission to request an Authority Required (STREAMLINED) listing for prophylaxis in patients with chronic migraine. |
| New listing(Major Submission) | EXENATIDEInjection 2 mg in 0.85 mL single dose autoinjectorBydureon® BCise®AstraZeneca Pty Ltd  | Type 2 diabetes mellitus (T2DM) | To request an Authority Required (STREAMLINED) listing for use in combination with metformin or sulfonylurea for the treatment of patients with T2DM. |
| Change to listing(Major Submission) | FLUTICASONE FUROATE with UMECLIDINIUM and VILANTEROLPowder for oral inhalation in breath actuated device containing fluticasone furoate 100 micrograms with umeclidinium 62.5 micrograms (as bromide) and vilanterol 25 micrograms (as trifenatate) per dose, 30 dosesTrelegy® Ellipta®GlaxoSmithKline Australia Pty Ltd | Chronic Obstructive Pulmonary Disease (COPD) | To request a change to the current clinical criteria to remove the requirement for patients to have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy. |
| Change to listing(Minor Submission) | INFLIXIMABPowder for I.V. infusion 100 mgInflectra®Pfizer Australia Pty Ltd  | Crohn diseaseFistulating Crohn diseaseUlcerative colitisAnkylosing spondylitisPsoriatic arthritisChronic plaque psoriasis | To request an increase in the maximum quantity of vials from 4 to 5 in the Authority Required (STREAMLINED), subsequent continuing treatment phase for indications for which a 5 mg/kg dose regimen is required. |
| New listing(Major Submission) | INSULIN GLARGINE with LIXISENATIDEInjections (human analogue), cartridges, insulin glargine 100 units per mL with lixisenatide 50 micrograms per mL, 3 mL, 5Injections (human analogue), cartridges, insulin glargine 100 units per mL with lixisenatide 33 micrograms per mL, 3 mL, 5Soliqua®Sanofi-Aventis Australia Pty Ltd | Type 2 diabetes mellitus (T2DM) | Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with T2DM who have inadequate glycaemic control with basal insulin. |
| Change to listing(Major Submission) | IVACAFTORSachet containing granules 50 mgSachet containing granules 75 mgKalydeco®Vertex Pharmaceuticals (Australia) Pty Ltd | Cystic fibrosis (CF) | To request an extension to the current Section 100 (Highly Specialised Drugs Program) Authority Required listing to include the treatment of CF in patients aged 12–24 months who have at least one *G551D* or other gating (class III) mutation in the CF transmembrane conductance regulator (CFTR) gene. |
| Change to listing(Minor Submission) | LANREOTIDEInjection 120 mg (as acetate) in single dose pre-filled syringeSomatuline® Autogel®Ipsen Pty Ltd  | Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NETs)  | To request a Section 100 (Highly Specialised Drug - Community Access), Authority Required (STREAMLINED) listing for the treatment of GEP-NETs.  |
| Change to listing(Major 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.  |
| Change to listing(Minor Submission) | LENALIDOMIDECapsule 5 mgCapsule 10 mgCapsule 15 mgCapsule 25 mgRevlimid®Celgene Pty Ltd | Multiple myeloma | To request the current Authority Required (written) listings of lenalidomide for multiple myeloma be amended to Authority Required (STREAMLINED).  |
| New listing(Major Submission) | LETERMOVIRTablet 240 mgPrevymis®Merck Sharp and Dohme (Australia) Pty Ltd  | Prophylaxis of cytomegalovirus (CMV) infection or disease | Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the prophylaxis of cytomegalovirus (CMV) infection or disease in adult CMV-seropositive [R+] recipients of an allogeneic haematopoietic stem cell transplant (allo-HSCT). |
| New listing(Major Submission) | LEVONORGESTRELIntrauterine drug delivery system 19.5 mgKyleena®Bayer Australia Ltd | Contraception | To request a Restricted Benefit listing for contraception. |
| Change to listing(Minor Submission) | MORPHINECapsule containing morphine sulfate pentahydrate 10 mg (modified release)Capsule containing morphine sulfate pentahydrate 20 mg (modified release)Kapanol®Mayne Pharma International Pty Ltd | Chronic breathlessness | To request a Restricted Benefit listing on the Palliative Care schedule for the treatment of chronic breathlessness. |
| New listing(Minor Submission) | NALOXONE2.2 mg/actuation nasal spray, 2 x 1 actuationNyxoid®Mundipharma Pty Ltd | Known or suspected opiate overdose | To request an unrestricted listing for known or suspected opiate overdose. |
| New listing(Major Submission) | NERATINIBTablet 40 mg Nerlynx®Specialised Therapeutics Pty Ltd | Early breast cancer (eBC) | To request an Authority Required listing for extended adjuvant treatment of patients with early-stage Human epidermal growth factor receptor-2 positive (HER2+) overexpressed/amplified breast cancer who have received prior adjuvant trastuzumab based therapy. |
| Change to 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 | MelanomaNon-small cell lung cancer Renal cell carcinoma Squamous cell carcinoma of the head and neck  | A request to amend the current 3mg/kg every two weeks (Q2W) dosing regimen of nivolumab for the treatment of unresectable Stage III or Stage IV malignant melanoma to include recent TGA approved changes to dosing and allow clinician choice of either:1. Weight-based 3mg/kg Q2W dosing, or2. Fixed 240mg Q2W dosing, or 3. Fixed 480mg Q4W dosing.  |
| Change to listing(Major 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) Authority Required (STREAMLINED) listing for the adjuvant treatment of patients who have had completely surgically resected Stage III or Stage IV malignant melanoma. |
| New listing(Minor Submission) | OCRIPLASMINSolution for intravitreal injection 0.375 mg in 0.3 mLJetrea® RTUiCare Pharma Distributors | Vitreomacular traction syndrome (VTS) | To request an Authority Required listing of a new form of ocriplasmin for VTS. |
| New listing(Major Submission)*Withdrawn* | OLARATUMABSolution concentrate for I.V. infusion 190 mg in 19 mLSolution concentrate for I.V. infusion 500 mg in 50 mLLartruvo®Eli Lilly Australia Pty Ltd  | Soft tissue sarcoma | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing, in combination with doxorubicin, for the treatment of patients with locally advanced or metastatic soft tissue sarcoma not amenable to curative treatment with radiotherapy or surgery.  |
| New listing(Minor Submission) | PACLITAXEL, NANOPARTICLE ALBUMIN-BOUND Powder for I.V. injection containing 250 mg paclitaxelAbraxane®Specialised Therapeutics Pty Ltd | Adenocarcinoma of the pancreasBreast cancer | To request an Authority Required (STREAMLINED) listing of a new vial size.  |
| Change to listing(Minor Submission) | PEGVISOMANTInjection set containing powder for injection 10 mg, 30 and diluent, 30Injection set containing powder for injection 15 mg, 30 and diluent, 30Injection set containing powder for injection 20 mg, 30 and diluent, 30Injection set containing powder for injection 20 mg, 1 and diluent, 1Somavert®Pfizer Australia Pty Ltd | Acromegaly | To request a change to the definition of failure to achieve biochemical control in the current PBS restriction.  |
| Change to listing(Major Submission) | PEMBROLIZUMABSolution concentrate for I.V. infusion 100 mg in 4 mLKeytruda®Merck Sharp and Dohme (Australia) Pty Ltd  | Metastatic colorectal carcinoma (CRC) | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of locally advanced or metastatic CRC in patients with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumours, who have progressed following prior treatment.  |
| Change to listing(Major Submission) | PERTUZUMABSolution for I.V. infusion 420 mg in 14 mLPerjeta®Roche Products Pty Ltd | Early breast cancer (eBC) | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing in combination with trastuzumab and chemotherapy, for the adjuvant treatment of human epidermal growth factor receptor-2 positive (HER2+) lymph node positive eBC. |
| Change to listing(Minor Submission) | QUADRIVALENT INFLUENZA VACCINE0.5 mL pre-filled syringeFluarix Tetra®GlaxoSmithKline Australia Pty Ltd | Influenza | To request an extension of the National Immunisation Program listing of the Fluarix® Tetra brand to include children aged 6 months to 3 years of age. |
| New listing(Minor Submission) | RITUXIMABSolution for I.V. infusion 100 mg in 10 mLSolution for I.V. infusion 500 mg in 50 mLTruxima®Celltrion Healthcare Australia Pty. Ltd. | Non-Hodgkin lymphoma | To request a Section 100 (Efficient Funding of Chemotherapy) listing of a biosimilar rituximab for the treatment of CD20 positive B-cell non-Hodgkin lymphoma under the same conditions as the reference biologic. |
| New listing(Major Submission) | RIVAROXABANTablet 2.5 mg Xarelto®Bayer Australia Ltd | Coronary Artery Disease (CAD) and Peripheral Artery Disease (PAD) | To request an Authority Required (STREAMLINED) listing for treatment of patients at high risk of recurrent cardiovascular events in the stable phase of CAD and/or PAD.  |
| New listing(Minor Submission) | SEVELAMERTablet containing sevelamer carbonate 800 mgSevelamer Dr Reddy's®Dr Reddy's | Hyperphosphataemia | To request Section 100 (Highly Specialised Drug Program) and Section 85 Authority Required (STREAMLINED) listings for the treatment of hyperphosphataemia in adult patients with chronic kidney disease who are on dialysis. |
| New listing(Major Submission) | SODIUM PHENYLBUTYRATEGranules 483 mg (as sodium) per g, 174 gPheburane®Orpharma Pty Ltd | Urea cycle disorders (UCD) | Resubmission to request an Authority Required listing for the treatment of patients with UCD. |
| New listing(Major Submission) | TEDUGLUTIDEPowder for injection 5 mg with diluentRevestive®Shire Australia Pty Limited | Short Bowel Syndrome (SBS) | Resubmission to request a Section 100 (Highly Specialised Drug) Authority Required listing for the treatment of SBS in patients who are dependent on parenteral nutrition for survival. |
| New listing(Major Submission) | TEZACAFTOR with IVACAFTORTablet containing tezacaftor 100 mg with ivacaftor 150 mgSymdeko®Vertex Pharmaceuticals (Australia) Pty Ltd | Cystic fibrosis (CF) | To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of CF in patients aged over 12 years:* who are homozygous for the *F508del* mutation in the CF transmembrane conductance regulator (CFTR) gene; or
* who have at least one residual function (RF) mutation in the CFTR gene.
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| New listing(Minor Submission) | TIOTROPIUMCapsule containing powder for oral inhalation 13 microgram (for use in Zonda device)Braltus®TEVA Australia Pty Ltd | Chronic obstructive pulmonary disease (COPD) | To request a Restricted Benefit listing for the treatment of COPD. |
| Other business(Minor Submission) | TIOTROPIUMCapsule containing powder for oral inhalation 18 micrograms (for use in HandiHaler)Spiriva®Boehringer-Ingelheim Pty Ltd | Chronic obstructive pulmonary disease (COPD) | To request that Spiriva and Braltus brands of tiotropium not be 'a' flagged.  |
| Change to listing(Minor Submission) | TOCILIZUMABInjection 162 mg in 0.9 mL single use pre-filled penInjection 162 mg in 0.9 mL single use pre-filled syringe Actemra®Roche Products Pty Ltd | Polyarticular juvenile idiopathic arthritis (pJIA).  | To request an extension of the current Authority Required listing of subcutaneous tocilizumab to include pJIA.  |
| Change to listing(Minor Submission) | TOCILIZUMABInjection 162 mg in 0.9 mL single use pre-filled penActemra®Roche Products Pty Ltd | Giant Cell Arteritis | Resubmission to request an Authority Required listing for the treatment of giant cell arteritis. |
| Change to listing(Major Submission) | TOFACITINIBTablet 5 mgTablet 10 mgXeljanz®Pfizer Australia Pty Ltd | Ulcerative Colitis (UC) | To request an Authority Required listing for the treatment of moderate to severe UC in adult patients who have had an inadequate response or failure of standard medical management (5-aminosalicylates [5-ASAs], thiopurines and/or a course of corticosteroids) according to the Mayo endoscopy score, or intolerance to these treatments. |
| New listing(Minor Submission) | TRASTUZUMABPowder for I.V. infusion 150 mgPowder for I.V. infusion 440 mg with diluentOgivri® Alphapharm Pty Ltd | Breast cancerGastric cancer | To request a Section 100 (Efficient Funding of Chemotherapy) listing of a biosimilar trastuzumab under the same conditions as the reference biologic. |
| New listing(Minor Submission) | TRASTUZUMABPowder for I.V. infusion 150 mgOntruzant®Merck Sharp & Dohme (Australia) Pty Limited  | Breast cancerGastric cancer  | To request a Section 100 (Efficient Funding of Chemotherapy) listing of a biosimilar trastuzumab under the same conditions as the reference biologic. |
| Change to listing(Minor Submission) | TRIGLYCERIDES - MEDIUM CHAIN, FORMULAOral liquid 500mL, 12 (Nutrini Peptisorb)Oral liquid 500 mL, 12 (Nutrini Peptisorb Energy)Nutrini Peptisorb®Nutrini Peptisorb Energy®Nutricia Australia Pty Limited | Dietary management of conditions requiring a source of medium chain triglycerides | To request a change to the pack size and maximum quantities of Nutrini Peptisorb and Nutrini Peptisorb Energy. |
| Sub-committee report (DUSC Analysis) | Bendamustine (Ribomustin®,Janssen-Cilag Pty Ltd) | Stage III or IV indolent CD20 positive non-Hodgkins lymphoma and Mantle cell lymphoma | To compare the predicted and actual utilisation of bendamustine for the treatment of lymphoma in the first 24 months of PBS listing. |
| Sub-committee report(DUSC Analysis) | Eculizumab (Soliris®, Alexion Pharmaceuticals Australasia Pty Ltd) | Atypical haemolytic uraemic syndrome | To complete a brief review to report on the number of initiating and prevalent patients, and the extent of continuation, stopping and restarting therapy. |
| Matters relating to the Post-market Review of Pulmonary Arterial Hypertension (PAH) Medicines | Matters relating to the PBS review:BosentanAmbrisentanMacitentanEpoprostenolIloprostSildenafil, tablet 20mgTadalafil, tablet 20mg (56)Riociguat (all listed brands including generic versions) | Pulmonary Arterial Hypertension (PAH) | To consider the restriction amendments for PAH medicines as requested by the PBAC following consideration of the Post-market Review of PAH medicines in November 2018 |
| Other business | PEMBROLIZUMABSolution concentrate for I.V. infusion 100 mg in 4 mLKeytruda®Merck Sharp and Dohme (Australia) Pty Ltd  | First-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) expressing PD-L1 TPS>50%. | The Department is seeking the advice of the PBAC on the clinical and economic analyses for pembrolizumab when used for the first line treatment of patients with metastatic non-small cell lung cancer (NSCLC) expressing PD-L1 TPS > 50% as recommended for PBS listing in July 2018 in light of the availability of new clinical trial data.  |