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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 Type and Use**(What is the drug used to treat?) | **Listing requested by Sponsor / Purpose of Submission**(Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased.) |
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| New listing(Minor Submission) | ADALIMUMABInjection 80 mg in 0.8 mL pre-filled penInjection 80 mg in 0.8 mL pre-filled syringeHumira®AbbVie Pty Ltd | Moderate to severe hidradenitis suppurativa | To request an Authority Required listing of a new form of adalimumab for the treatment of patients with hidradenitis suppurativa under the same conditions as current listings. |
| New listing(Minor Submission) | AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINETablets 0.92g, 462PKU Easy® TabletOrpharma Pty Ltd | Phenylketonuria (PKU) | To request a Restricted Benefit listing for the dietary management of patients with PKU. |
| New listing(Minor Submission) | AMINO ACID FORMULA WITH FAT, CARBOHYDRATE WITHOUT PHENYLALANINE AND TYROSINETablets 0.91g, 462TYR Easy® TabletOrpharma Pty Ltd | Tyrosinaemia | To request a Restricted Benefit listing for the dietary management of patients with tyrosinaemia. |
| New listing(Minor Submission) | AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, WITHOUT METHIONINETablets 0.91g, 462HCU Easy® TabletOrpharma Pty Ltd | Pyridoxine non-responsive homocystinuria | To request a Restricted Benefit listing for the dietary management of patients with pyridoxine non-responsive homocystinuria. |
| New listing(Minor Submission) | AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, WITHOUT VALINE, LEUCINE AND ISOLEUCINETablets 0.91g, 462MSUD Easy® TabletOrpharma Pty Ltd | Maple syrup urine disease | To request a Restricted Benefit listing for the dietary management of patients with maple syrup urine disease. |
| New Listing(Minor Submission) | AMINO ACID FORMULA WITH VITAMINS WITH MINERALS, WITHOUT VALINE, LEUCINE AND ISOLEUCINE WITH DOCOSOHEXAENOIC ACID AND ARACHIDONIC ACID (MSUD EXPLORE)Sachet containing oral powder 12.5 g, 30MSUD explore® 5Vitaflo Australia Pty Limited | Maple syrup urine disease | To request a Restricted Benefit listing for the dietary management of patients with maple syrup urine disease. |
| Change to listing(Minor Submission) | ATEZOLIZUMABSolution concentrate for I.V. infusion 1200 mg in 20 mLTecentriq®Roche Products Pty Ltd | Small cell lung cancer (SCLC) | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first-line treatment of patients with extensive stage SCLC.  |
| Change to listing(Minor Submission) | ATEZOLIZUMABSolution concentrate for I.V. infusion 840 mg in 14 mLTecentriq®Roche Products Pty Ltd | Non-small cell lung cancer (NSCLC) | To request the addition of a new vial size and to amend the current dosing regimen of atezolizumab for second-line NSCLC and the recommended listing for first-line NSCLC to allow clinician choice of either:* 1,200 mg Q3W dosing, or
* 1,680 mg Q4W dosing.
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| New listing(Major Submission) | BELIMUMABInjection 200 mg in 1 mL pre-filled penBenlysta® GlaxoSmithKline Australia Pty Ltd | Systemic lupus erythematosus (SLE) | To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of patients with highly active auto-antibody positive SLE. |
| Change to listing(Minor Submission) | BOTULINUM TOXIN TYPE A PURIFIED NEUROTOXIN COMPLEXLyophilised powder for injection 100 unitsBotox®Allergan Australia Pty Limited | Spasticity of the upper limb  | To request an extension to the current Section 100 (Botulinum Toxin Program) Authority Required (STREAMLINED) listing for moderate to severe spasticity of the upper limb following a stroke to include the treatment of patients with moderate to severe spasticity of the upper limb following an acute event, consistent with the March 2019 PBAC recommendation for clostridium botulinum type A (Dysport®). |
| New listing (Major Submission) | BRIGATINIB Tablet 30 mgTablet 90 mgTablet 180 mgPack containing 7 tablets containing brigatinib 90 mg and 21 tablets containing brigatinib 180 mgAlunbrig® Takeda Pharmaceuticals Australia Pty Ltd | Non-small cell lung cancer (NSCLC) | To request an Authority Required listing for the treatment of patients with locally advanced or metastatic anaplastic lymphoma kinase positive NSCLC.  |
| Change to listing(Major Submission) | BRIVARACETAMTablet 25 mgTablet 50 mgTablet 75 mgTablet 100 mgOral solution 10mg per mL, 300 mLBriviact® UCB Australia Proprietary Limited | Epilepsy | To request a change to the current Authority Required (STREAMLINED) listings for the treatment of patients with intractable partial epileptic seizures, to allow use in patients aged less than 16 years. |
| New listing(Major Submission) | BROLUCIZUMABSolution for intravitreal injection 19.8 mg in 0.165 mL pre-filled syringeBeovu®Novartis Pharmaceuticals Australia Pty Limited | Subfoveal choroidal neovascularisation (CNV)  | To request an Authority Required listing for the treatment of patients with CNV due to age-related macular degeneration.  |
| New listing(Minor Submission) | BUDESONIDE WITH FORMOTEROLPowder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 dosesPressurised 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  | Resubmission to request an Authority Required (STREAMLINED) listing for the first-line treatment of patients with mild asthma. |
| New listing(Minor submission) | BUPRENORPHINE100 mg/0.5 mL modified release injection, 0.5 mL syringe300 mg/1.5 mL modified release injection, 1.5 mL syringeSublocade®Indivior Pty Ltd | Opiate dependence | Consider the deferred request for a Section 100 (Opiate Dependence Treatment Program) listing for the treatment of patients with opioid use disorder. |
| New listing(Major Submission) | BUPRENORPHINE WITH NALOXONETablet (sublingual) containing 0.7 mg buprenorphine hydrochloride with 0.18 mg naloxone hydrochlorideTablet (sublingual) containing 1.4 mg buprenorphine hydrochloride and 0.36 mg naloxone hydrochlorideTablet (sublingual) containing 2.9 mg buprenorphine hydrochloride and 0.71 mg naloxone hydrochlorideTablet (sublingual) containing 5.7 mg buprenorphine hydrochloride and 1.4 mg naloxone hydrochlorideTablet (sublingual) containing 8.6 mg and 2.1 mg naloxone hydrochlorideTablet (sublingual) containing 11.4 mg buprenorphine hydrochloride and 2.9 mg naloxone hydrochlorideZubsolv®Mundipharma Pty Limited | Opiate dependence | To request a Section 100 (Opiate Dependence Treatment Program) Restricted Benefit listing for the treatment of patients with opiate dependence. |
| Change to listing(Major Submission) | CERTOLIZUMAB PEGOLInjection 200 mg in 1 mL single use pre-filled syringe Solution for injection 200 mg in 1 mL pre-filled penCimzia®UCB Australia Proprietary Limited | Non-radiographic axial sponyloarthritis (nr-axSpA) | To request an Authority Required listing for the treatment of patients with nr-axSpA who meet certain conditions. |
| Change to recommended listing(Minor Submission) | CERTOLIZUMAB PEGOLInjection 200 mg in 1 mL single use pre-filled syringe Solution for injection 200 mg in 1 mL pre-filled penCimzia®UCB Australia Proprietary Limited | Chronic plaque psoriasis (CPP) | Resubmission to request reconsideration of the basis of the PBAC’s March 2019 recommendation for the Authority Required listing for the treatment of patients with CPP. |
| New listing(Major Submission) | DARATUMUMABSolution concentrate for I.V infusion 100 mg in 5 mLSolution concentrate for I.V infusion 400 mg in 20 mLDarzalex®Janssen-Cilag Pty Ltd | Multiple myeloma | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing, in combination with bortezomib and dexamethasone, for the treatment of patients with relapsed or refractory multiple myeloma who have progressive disease after one prior line of therapy.  |
| New listing (Major Submission) | DARUNAVIR with COBICISTAT with EMTRICITABINE and TENOFOVIR ALAFENAMIDETablet containing darunavir 800 mg with cobicistat 150 mg with emtricitabine 200 mg and tenofovir alafenamide 10 mg Symtuza®Janssen-Cilag 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. |
| Change to listing(Minor Submission) | DIMETHYL FUMARATECapsule (modified release) 120 mgCapsule (modified release) 240 mgTecfidera®Biogen Australia Pty Ltd | Relapsing-remitting multiple sclerosis (RRMS) | To request the current Authority Required listings of dimethyl fumarate for the treatment of patients with RRMS be changed to Authority Required (STREAMLINED). |
| Change to listing (Major Submission) | DULAGLUTIDEInjection 1.5 mg in 0.5 mL single dose pre-filled penTrulicity®Eli Lilly Australia Pty Ltd | Type 2 diabetes mellitus (T2DM) | To request an Authority Required (STREAMLINED) listing for use in combination with insulin and metformin for the treatment of patients with T2DM.  |
| New listing(Minor Submission) | DURVALUMABSolution concentrate for I.V. infusion 120 mg in 2.4 mLSolution concentrate for I.V. infusion 500 mg in 10 mLImfinzi®AstraZeneca 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(Major Submission)*Withdrawn* | ERENUMABInjection 70 mg in 1 mL single dose pre-filled penInjection 140 mg in 1 mL single dose pre-filled penAimovig®Novartis Pharmaceuticals Australia Pty Limited | Chronic migraine | Resubmission to request an Authority Required (STREAMLINED) listing for the prophylactic treatment of adult patients with chronic migraine who have experienced inadequate response, intolerance or a contraindication to at least three prior preventive migraine medications. |
| Change to listing(Minor 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 for atherosclerotic cardiovascular disease (ASCVD) or inadequately controlled on optimal doses of high potency statins and ezetimibe. |
| New listing(Major Submission) | FREMANEZUMABInjection 225 mg in 1.5 mL pre-filled syringeAjovy®Teva Pharma Australia Pty Limited | Chronic migraine | To request an Authority Required (STREAMLINED) listing for the prophylactic treatment of adult 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) | GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALSSachets containing oral powder 16 g, 60Sachets containing oral powder 32 g, 30PKU Build® 10 PKU Build® 20Cortex Health Pty Ltd | Phenylketonuria | To request changes to the formulation of PKU Build 10 and PKU Build 20. |
| Change to listing(Major Submission) | HIGH DOSE INACTIVATED TRIVALENT INFLUENZA VACCINE (SPLIT VIRION)Injection 0.5 mLFluzone® High-DoseSanofi-Aventis Australia Pty Ltd | Prevention of seasonal influenza | Resubmission to request that the PBAC review the basis of its March 2018 recommendation for National Immunisation Program (NIP) listing for the prevention of seasonal influenza in patients aged 65 years and over.  |
| Change to listing(Major Submission) | IBRUTINIBCapsule 140 mgImbruvica® Janssen-Cilag Pty Ltd | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) | Resubmission to request an Authority Required listing for the treatment of patients with previously untreated CLL or SLL with evidence of one or more 17p chromosomal deletions. |
| Change to listing(Major Submission) | INACTIVATED QUADRIVALENT INFLUENZA VACCINE (SPLIT VIRION)Injection 0.5 mL FluQuadri®Sanofi-Aventis Australia Pty Ltd | Prevention of seasonal influenza | To request an extension to the current National Immunisation Program (NIP) listing to include all people aged 6 months and older currently eligible for seasonal influenza vaccination under the NIP for the prevention of seasonal influenza. |
| Change to listing(Minor Submission) | INCOBOTULINUMTOXIN ALyophilised powder for injection 100 unitsXeomin®Merz Australia Pty Ltd | Spasticity of the upper limb  | To request an extension to the current Section 100 (Botulinum Toxin Program) Authority Required (STREAMLINED) listing for moderate to severe spasticity of the upper limb following a stroke to include the treatment of patients with moderate to severe spasticity of the upper limb following an acute event, consistent with the March 2019 PBAC recommendation for clostridium botulinum type A (Dysport®). |
| New listing(Minor Submission) | ISOTRETINOINCapsule 30 mgOratane®Oraderm Pharmaceuticals Pty Ltd | Severe cystic acne | To request an Authority Required (STREAMLINED) listing of a new form of isotretinoin for the treatment of patients with severe cystic acne.  |
| Change to listing(Minor Submission) | LEVODOPA with CARBIDOPAIntestinal gel containing levodopa 20 mg with carbidopa monohydrate 5 mg per mL, 100 mLDuodopa®AbbVie Pty Ltd | Parkinson disease | To request: * General Schedule and Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listings with a new maximum quantity of 4 packs, with the same listing conditions as the current listings.
* An additional clinical criterion for the current listings: 'patient must require continuous administration without an overnight break or a total dose per day of levodpa > 2000 mg'
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| New listing(Major Submission) | LORLATINIB Tablet 25 mgTablet 100 mg Lorviqua® Pfizer Australia Pty Ltd | Non-small cell lung cancer (NSCLC) | To request an Authority Required listing for the treatment of patients with metastatic anaplastic lymphoma kinase (ALK) positive NSCLC previously treated with one or more ALK tyrosine kinase inhibitors. |
| New listing(Major Submission) | MULTICOMPONENT MENINGOCOCCAL GROUP B VACCINE Injection 0.5 mL Bexsero®GlaxoSmithKline Australia Pty Ltd | Prevention of meningococcal B disease | Resubmission to request listing on the National Immunisation Program (NIP) for the routine immunisation of infants and adolescents, and catch-up programs for high risk populations for the prevention of IMD caused by *N. meningitidis* group B strains. |
| New listing(Major Submission) | NERATINIBTablet 40 mg Nerlynx®Specialised Therapeutics Australia Pty Ltd | Early breast cancer | Resubmission to request an Authority Required listing for extended adjuvant treatment of patients with human epidermal growth factorreceptor-2 positive (HER2+) early breast cancer who have received prior adjuvant trastuzumab therapy. |
| New Listing(Minor Submission) | NUSINERSENSolution for injection 12 mg in 5 mLSpinraza®Biogen Australia Pty Ltd | Spinal muscular atrophy | Consider the deferred request for 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. |
| Change to listing(Major Submission) | NIVOLUMAB Nivolumab: Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mLOpdivo®IPILIMUMABIpilimumab: Injection concentrate for I.V. infusion 50 mg in 10 mL Injection concentrate for I.V. infusion 200 mg in 40 mLYervoy®Bristol-Myers Squibb Australia Pty Ltd | Melanoma | Resubmission to request an extension of the current Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listings for nivolumab and ipilimumab for the treatment of unresectable Stage III or IV malignant melanoma to allow use as first-line therapies in patients who are BRAF V600 mutation positive. |
| Change to listing(Major Submission) | OLAPARIBTablet 100 mgTablet 150 mg Lynparza®AstraZeneca Pty Ltd | Ovarian, fallopian tube or primary peritoneal cancer | To request an Authority Required listing for the maintenance treatment of advanced high grade epithelial ovarian, fallopian tube or primary peritoneal cancer, in class 4 or 5 BRCA1/2 mutation positive patients who are in response to platinum-based chemotherapy. |
| New listing(Major Submission) | PATIROMERPowder for oral liquid 8.4 gPowder for oral liquid 16.8 gVeltassa®Vifor Pharma Pty Limited | Hyperkalaemia | To request an Authority Required listing for the prevention of hyperkalaemia in patients with stage III or greater chronic kidney disease who have experienced a recent episode of hyperkalaemia requiring pharmacological intervention. |
| New listing(Minor Submission) | PEGFILGRASTIMInjection 6 mg in 0.6 mL single use pre-filled syringeZiextenzo®Sandoz Pty Ltd | Chemotherapy-induced neutropenia | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing of a biosimilar pegfilgrastim under the same conditions as the reference biologic. |
| Change to listing(Minor Submission) | PEMBROLIZUMABSolution concentrate for I.V. infusion 100 mg in 4 mLKeytruda®Merck Sharp & Dohme (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 IIIB-D malignant melanoma. |
| New listing(Major Submission) | POLATUZUMAB VEDOTINPowder for I.V. infusion 140 mgPolivy®Roche Products Pty Ltd | Diffuse large B-cell lymphoma (DLBCL) | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of patients with relapsed or refractory DLBCL who are ineligible for stem cell transplantation. |
| Change to listing(Minor Submission) | POMALIDOMIDECapsule 3 mgCapsule 4 mgPomalyst®Celgene Pty Ltd | Multiple myeloma | Resubmission 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 listing(Minor Submission) | PREDNISOLONE ACETATE WITH PHENYLEPHRINEEye drops containing prednisolone acetate 10 mg with phenylephrine hydrochloride 1.2 mg per mL, 10 mLPrednefrin® ForteNational Aboriginal Community Controlled Health Organisation | Severe inflammation of the eye | To request a Restricted Benefit listing for the treatment of severe inflammation of the eye following cataract surgery for patients who identify as Aboriginal and Torres Strait Islander. |
| New Listing(Minor Submission) | PROTEIN FORMULA WITH VITAMINS AND MINERALS, AND LOW IN POTASSIUM, PHOSPHORUS, CALCIUM, CHLORIDE AND VITAMIN AOral liquid 125 mL, 24Renastep®Vitaflo Australia Pty Limited | Chronic kidney disease (CKD) | To request an Authority Required (STREAMLINED) listing for the dietary management of paediatric CKD in patients aged 3 years and over who require a modified protein diet. |
| Change to listing(Major Submission) | RUXOLITINIBTablet 5 mgTablet 10 mgTablet 15 mgTablet 20 mgJakavi®Novartis Pharmaceuticals Australia Pty Limited | Polycythemia vera (PV) | To request an Authority Required listing for the treatment of patients with PV who are resistant to or intolerant of hydroxycabamide (hydroxyurea). |
| New Listing(Minor Submission) | SALBUTAMOLPressurised inhalation 100 micrograms (as sulfate) per dose, 200 doses (CFC-free formulation)Ventolin®GlaxoSmithKline Australia Pty Ltd | Asthma;Chronic obstructive pulmonary disease (COPD) | To request an Unrestricted Benefit listing of a new presentation of salbutamol metered dose inhaler with a dose counter. |
| New listing(Major Submission) | SEMAGLUTIDEInjection 2 mg in 1.5 mL pre-filled syringeInjection 4 mg in 3 mL pre-filled syringeOzempic® Novo Nordisk Pharmaceuticals Pty Limited | Type 2 diabetes mellitus (T2DM) | To request an Authority Required (STREAMLINED) listing for use in combination with metformin and/or a sulfonylurea for the treatment of patients with T2DM. |
| New listing(Major Submission) | SIPONIMODTablet 250 microgramsTablet 2 mg Mayzent®Novartis Pharmaceuticals Australia Pty Limited | Secondary progressive multiple sclerosis (SPMS) | To request an Authority Required listing for the treatment of patients with SPMS.  |
| New listing(Minor Submission) | TACROLIMUSCapsule 3 mg (once daily prolonged release)Advagraf XL®Astellas Pharma Australia Pty Ltd | Management of rejection in patients following organ or tissue transplantation | To request an unrestricted General Schedule listing and a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing of a new form of tacrolimus under the same conditions as the current 500 microgram, 1 mg and 5 mg prolonged-release listings. |
| New listing(Major Submission) | TALAZOPARIBCapsule 250 micrograms (as tosilate)Capsule 1 mg (as tosilate) Talzenna®Pfizer Australia Pty Ltd | Advanced breast cancer | To request an Authority Required listing for the treatment of patients with germline BRCA mutated HER2-negative advanced breast cancer who have been previously treated with a taxane and/or an anthracycline.  |
| Change to recommended listing(Minor Submission) | TEZACAFTOR WITH IVACAFTORTablet containing tezacaftor 100 mg with ivacaftor 150 mgSymdeko®Vertex Pharmaceuticals (Australia) Pty Ltd | Cystic Fibrosis (CF) | Resubmission to request an extension to the PBAC’s March 2019 recommendation for Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of CF in patients aged 12 years or older who have one copy of the F508del mutation and another residual function (RF) mutation in the CF transmembrane conductance regulator (CFTR) gene to be for patients aged 12 years or older who have at least one copy of the RF mutation in the CFTR gene. |
| New listing(Minor Submission) | TOLVAPTANTablet 15 mg Tablet 30 mgPack containing 28 tablets 15 mg and 28 tablets 45 mg Pack 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: * listing of two new forms (15 mg and 30 mg tablets) of tolvaptan for the treatment of patients with ADPKD;
* to change the current General Schedule listings of tolvaptan to Section 100 (Highly Specialised Drugs Program - Community Access); and
* to change the authority level for initial treatment from a written to telephone authority.
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| Change to listing(Major Submission) | TRASTUZUMAB EMTANSINEPowder for I.V. infusion 100 mgPowder for I.V. infusion 160 mgKadcyla®Roche Products Pty Ltd | Early breast cancer | To request an Authority Required Section 100 (Efficient Funding of Chemotherapy Program) listing for the adjuvant treatment of patients with Human epidermal growth factor receptor-2 positive (HER2+) early breast cancer with residual disease following neoadjuvant treatment with HER2-targeted therapy.  |
| New listing(Minor Submission) | TRASTUZUMABPowder for I.V. infusion 60 mgPowder for I.V. infusion 150 mgTrazimera® Pfizer 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(Major Submission) | TRIFLURIDINE with TIPIRACILTablet containing 15 mg trifluridine with 6.14 mg tipiracil (as hydrochloride)Tablet containing 20 mg trifluridine with 8.19 mg tipiracil (as hydrochloride)Lonsurf®Servier Laboratories (Aust.) Pty Ltd | Gastric cancer | To request an Authority Required (STREAMLINED) listing for the treatment of patients with metastatic gastric cancer who have been previously treated with, or are not considered candidates for, currently available therapies.  |
| New listing(Major Submission) | UPADACITINIBTablet (modified release) 15 mgTrade name to be determinedAbbVie Pty Ltd | Rheumatoid arthritis (RA) | To request an Authority Required listing for the treatment of patients with severe active RA. |
| Sub-committee report(DUSC Analysis) | LenalidomideRevlimid®Celgene Pty Limited | Multiple Myeloma. | To compare the 24 month predicted and actual utilisation of lenalidomide as first line therapy for patients with newly diagnosed multiple myeloma. |
| Sub-committee report (DUSC Analysis) | Imatinib(Cipla imatinib adult®, Cipla Australia Pty Ltd); (Glivanib®, Juno Pharmaceuticals Pty Ltd);(Glivec®, Alphapharm Pty Ltd);(IMATINIB AN®, Juno Pharmaceuticals Pty Ltd);(Imatinib-APOTEX®, Apotex Pty Ltd);(IMATINIB-DRLA®, Dr Reddy's Laboratories (Australia) Pty Ltd);(Imatinib GH®, Generic Health Pty Ltd);(IMATINIB RBX®, Sun Pharma ANZ Pty Ltd);(Imatinib-Teva®, Sandoz Pty Ltd)Nilotinib(Tasigna®, Novartis Pharmaceuticals Australia Pty Limited)Dasatinib(Sprycel®, Bristol-Myers Squibb Australia Pty Ltd)Ponatinib (Iclusig ®, Specialised Therapeutics Australia Pty Ltd) | Chronic myeloid leukaemia (CML) | To analyse the utilisation of PBS-listed tyrosine kinase inhibitors (TKIs), imatinib, dasatinib, nilotinib and ponatinib, for the treatment of CML, as requested by DUSC at its June 2019 meeting. |
| Sub-committee report(DUSC Analysis) | Omalizumab (Xolair® Novartis Pharmaceuticals Australia Pty Limited)Mepolizumab (Nucala®, GlaxoSmithKline Australia Pty Ltd)Benralizumab (Fesenra®, AstraZeneca Pty Ltd) | Severe allergic and eosinophilic asthma | Review of biologics for uncontrolled severe allergic and eosinophilic asthma  |
| Sub-committee report(DUSC Analysis) | Evolocumab(Repatha®, Amgen Australia Pty Limited) | Familial homozygous hypercholesterolaemia  | To compare the predicted and actual utilisation of evolocumab for homozygous familial hypercholesterolaemia since PBS listing on 1 December 2016. |