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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 Services 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(Major submission) | ABEMACICLIBTablet 50 mgTablet 100 mgTablet 150 mgVerzenio®Eli Lilly Australia Pty Ltd | Breast cancer | To request an Authority Required (Telephone/Online) listing for the treatment of hormone receptor positive (HR+) and/or human epidermal growth factor receptor 2 negative (HER2-) inoperable locally advanced or metastatic breast cancer. |
| New listing(Minor submission) | ACICLOVIREye ointment 30 mg per g, 4.5 gXorox®Clinect Pty Ltd | Herpes simplex keratitis | To request a Restricted Benefit listing for a new brand of aciclovir for the treatment of Herpes simplex keratitis under the same conditions as the currently listed aciclovir eye ointment.  |
| New listing(Minor submission) | AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDESOral powder 800 gEssential Care JrCortex Health Pty Ltd | Multiple food allergies and various gastrointestinal disorders and allergic conditions | To request an Authority Required (Telephone) listing for the treatment of a number of different GI intolerance and allergy indications under the same conditions as the currently listed comparator.  |
| Change to listing(Major submission) | ATEZOLIZUMABSolution concentrate for I.V. infusion 840 mg in 14 mLTecentriq®Roche Products Pty Ltd | Breast cancer | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the first-line treatment of metastatic triple negative breast cancer. |
| Change to listing (Minor submission) | AVELUMAB Solution concentrate for I.V. infusion 200 mg in 10 mLBavencio®Merck Healthcare Pty Ltd | Renal cell carcinoma (RCC) | Re-submission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing, in combination with axitinib, for the first-line treatment of patients with Stage IV clear cell variant RCC.  |
| Change to listing(Major submission) | AVELUMABSolution concentrate for I.V. infusion 200 mg in 10 mLBavencio®Merck Healthcare Pty Ltd | Urothelial carcinoma | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of locally advanced (Stage III) or metastatic (Stage IV) urothelial carcinoma. |
| Change to listing(Minor submission) | BEVACIZUMABSolution for I.V. infusion 100 mg in 4 mLSolution for I.V. infusion 400 mg in 16 mLMVASI®Amgen Australia Pty Ltd | Non-small cell lung cancer (NSCLC) | To request changes to the restriction wording for MVASI® for treatment of NSCLC under Section 100 (Efficient Funding of Chemotherapy).  |
| Change to listing(Major submission) | BRENTUXIMAB VEDOTINPowder for I.V. infusion 50 mgADCETRIS®Takeda Pharmaceuticals Australia Pty Ltd | T-cell lymphoma | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the first-line treatment of CD30 positive peripheral T-cell lymphoma. |
| New listing (Major submission) | BROLUCIZUMABSolution for injection 19.8 mg in 0.165 mL pre-filled syringeBeovu®Novartis Pharmaceuticals Australia Pty Ltd | Wet age-related macular degeneration (AMD) | To request an Authority Required (Written) listing for the treatment of neovascular (wet) aged-related macular degeneration. |
| New listing (Major submission) | BUDESONIDE Tablet (orally disintegrating) 1 mgJorveza®Dr Falk Pharma Australia Pty Ltd | Eosinophilic Oesophagitis (EoE) | To request an Authority Required (STREAMLINED) listing for the treatment of EoE. |
| New listing (Major submission) | BUROSUMAB Injection 10 mg in 1 mLInjection 20 mg in 1 mLInjection 30 mg in 1 mLCrysvita®Kyowa Kirin Australia Pty Ltd | X-linked hypophosphataemia | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of x-linked hypophosphataemia. |
| Changes to listing (Minor submission) | CABAZITAXELConcentrated injection containing cabazitaxel 60 mg in 6 mLCabazitaxel Ever PharmaInterpharma Pty Ltd | Prostate cancer | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for a new brand with a different form for the same conditions as the currently listed cabazitaxel.  |
| New listing (Major submission) | CABOTEGRAVIR/CABOTEGRAVIR AND RILPIVIRINETablet containing cabotegravir 30 mgVocabria®Pack containing 1 injection of cabotegravir 600 mg in 3 mL and 1 injection of rilpivirine 900 mg in 3mLCabenuva®ViiV Healthcare Pty Ltd | Human Immunodeficiency virus (HIV)  | To request a Section 100 (Highly Specialised Drugs Program - Community Access) Authority Required (STREAMLINED) listing for the treatment of HIV infection in adults who are virologically suppressed. |
| New listing (Major submission) | CICLOSPORIN Eye drops 0.1%, single dose units 0.4 mLIkervis®Seqirus (Australia) Pty Ltd | Dry eye disease in patients with keratitis | To request an Authority Required (STREAMLINED) listing for the treatment of dry eye disease with keratitis. |
| New listing (Major submission) | DAROLUTAMIDE Tablet 300 mgNubeqa®Bayer Australia Ltd | Prostate cancer | To request an Authority Required (Telephone) listing for the treatment of non-metastatic castration resistant carcinoma of the prostate. |
| New listing (Major submission) | DECITABINE AND CEDAZURIDINE Tablet containing decitabine 35 mg + cedazuridine 100 mgInqovi®Otsuka Australia Pharmaceutical Pty Ltd | Myelodysplastic syndromes (MDS) and chronic myelomonocytic leukaemia (CMML) | To request an Authority Required (non-immediate/delayed - In Writing only/Electronic) listing for the treatment of high risk MDS and CMML. |
| New listing (Major submission) | DEUTETRABENAZINETablet 6 mgTablet 9 mgTablet 12 mgAustedo®Teva Pharma Australia Pty Ltd | Chorea associated with Huntington's disease | To request an Authority Required listing for the treatment of mild, moderate and severe chorea associated with Huntington's disease. |
| New listing (Major submission) | ELEXACAFTOR/TEZACAFTOR/IVACAFTORPack containing 56 tablets of elexacaftor 100 mg with tezacaftor 50 mg and ivacaftor 75 mg and 28 tablets of ivacaftor 150 mgTrikafta®Vertex Pharmaceuticals (Australia) Pty Ltd | Cystic fibrosis | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of cystic fibrosis in patients aged 12 years or older who have at least one F508del mutation on the cystic fibrosis transmembrane conductance regulator (CFTR) gene. |
| Change to listing (Major submission) | ENCORAFENIBCapsule 50 mgCapsule 75 mgBraftovi®Pierre Fabre Australia Pty Ltd | Colorectal cancer | To request an Authority Required (STREAMLINED) listing for the treatment of BRAF V600E-variant metastatic (Stage IV) colorectal cancer. |
| New listing (Major submission) | ESLICARBAZEPINETablet 800 mgZebinix®Stada Pharmaceuticals Australia Pty Ltd | Epilepsy | To request an Authority Required (STREAMLINED) listing for the treatment of epilepsy in patients aged 16 years or older with partial onset seizures with or without secondary generalisation. |
| Change to listing(Minor submission) | EVOLOCUMABInjection 420 mg in 3.5 mL single use pre-filled cartridgeRepatha®Amgen Australia Pty Ltd | Familial heterozygoushypercholesterolaemia;Non-familial hypercholesterolaemia;Familial homozygoushypercholesterolaemia | To request an Authority Required listing for a new form of evolocumab under the same conditions as the already listed evolocumab 420 mg/3.5 mL pre-filled pen.  |
| New listing (Major submission)WITHDRAWN | FILGOTINIBTablet 100 mgTablet 200 mgJyseleca®Gilead Sciences Pty Ltd | Rheumatoid arthritis | To request an Authority Required (Written) listing for the treatment of severe active rheumatoid arthritis. |
| New listing (Major submission) | GEMTUZUMAB OZOGAMICIN Powder for injection 5 mgMylotarg®Pfizer Australia Pty Ltd | Acute myeloid leukaemia (AML)  | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Telephone/Online) listing for the treatment of de novo CD33-positive AML. |
| New Listing(Minor submission) | GLATIRAMERInjection containing glatiramer acetate 20 mg in 1 mL single dose pre-filled syringe Injection containing glatiramer acetate 40 mg in 1 mL single dose pre-filled syringe Glatira®Juno Pharmaceuticals Pty Ltd | Multiple sclerosis | To request an Authority Required (STREAMLINED) listing of a new brand with two different strengths under the same conditions as the currently listed glatiramer pre-filled syringe.  |
| New listing(Minor submission) | GUSELKUMABInjection 100 mg in 1 mL single use pre-filled penTremfya®Janssen-Cilag Pty Ltd | Severe Chronic Plaque Psoriasis (CPP) | To request an Authority Required (Written) listing for a new form for the treatment of severe CPP under the same conditions as the currently listed guselkumab injection syringe.  |
| Change to listing(Minor submission) | HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATEOral semi-solid, 100 g, 36 K.YoVitaflo Australia Pty Ltd | Dietary management of conditionsrequiring a ketogenic diet | To request a Restricted Benefit listing of a new brand with a different pack size and formulation. |
| Change to listing(Minor submission) | HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATEOral powder 300 gKetoCal 3:1KetoCal 4:1Nutricia Australia Pty Ltd | Ketogenic Diet | To request approval for changing the nutrient composition for the already listed KetoCal 3:1 and KetoCal 4:1.  |
| Change to listing (Major submission) | LACOSAMIDETablet 50 mgTablet 100 mgTablet 150 mgTablet 200 mgOral solution 10 mg per mL, 200 mLVimpat®UCB Australia Pty Ltd | Epilepsy | To request an Authority Required (STREAMLINED) listing for the treatment of idiopathic generalised epilepsy with primary generalised tonic-clonic seizures. |
| New listing (Major submission) | MELATONIN Tablet 1 mgTablet 5 mgSlenyto®Aspen Pharmacare Australia Pty Ltd | Insomnia | To request an Authority Required (Telephone/Online) listing for the treatment of insomnia in patients between the ages of 2 to 18 with autism spectrum disorder and/or Smith-Magenis syndrome. |
| Change to listing (Major submission) | NINTEDANIBCapsule 100 mgCapsule 150 mgOfev®Boehringer Ingelheim Pty Ltd | Progressive fibrosing interstitial lung disease (PF-ILD) | To request an Authority Required (Written) listing for the treatment of PF-ILD. |
| New listing (Major submission) | NIRAPARIBCapsule 100 mgZejula®GlaxoSmithKline Australia Pty Ltd | Ovarian, fallopian tube, or primary peritoneal cancer | To request an Authority Required (Telephone) listing for the treatment of platinum-sensitive, relapsed, high grade serous ovarian, fallopian tube or primary peritoneal cancer. |
| Change to listing(Minor submission) | NIVOLUMABInjection concentrate for I.V. infusion 40 mg in 4 mLInjection concentrate for I.V. infusion 100 mg in 10 mLOpdivo®Bristol-Myers Squibb Australia Pty Ltd | Non-small cell lung cancer (NSCLC) | Resubmission to address the PBAC’s concerns about the incremental effectiveness of nivolumab in patients 75 years or older. |
| Change to listing(Major submission) | NIVOLUMAB with IPILIMUMABNivolumab:Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mLOpdivo®Ipilimumab: Injection concentrate for I.V. infusion 50 mg in 10 mL Yervoy®Bristol-Myers Squibb Australia Pty Ltd | Malignant pleural mesothelioma | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the use of nivolumab in combination with ipilimumab for the treatment of malignant pleural mesothelioma. |
| New listing(Minor submission) | OBETICHOLIC ACIDTablet 5 mg, 10 mgOcaliva®Chiesi Australia Pty Ltd | Primary biliary cholangitis (PBC) | To request an Authority Required (Written) listing for the treatment of PBC. |
| New listing (Major submission) | OFATUMUMAB Injection 20 mg in 0.4 mL single use pre-filled penKesimpta®Novartis Pharmaceuticals Australia Pty Ltd | Multiple sclerosis (MS) | To request an Authority Required (STREAMLINED) listing for the treatment of MS. |
| Change to listing(Major submission) | OLAPARIB Tablet 100 mgTablet 150 mgLynparza®AstraZeneca Pty Ltd | Prostate cancer  | To request an Authority Required (Telephone/Online) listing for the treatment of metastatic castration resistant carcinoma of the prostate. |
| Change to listing(Major submission) | PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mLKeytruda®Merck Sharp & Dohme (Australia) Pty Ltd | Colorectal cancer | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of metastatic (Stage IV) mismatch repair deficient colorectal cancer. |
| New listing (Major submission) | RIPRETINIB Tablet 50 mgQinlock®Specialised Therapeutics PM Pty Ltd | Gastrointestinal stromal tumour | To request an Authority Required (Written) listing for the treatment of metastatic or unresectable malignant gastrointestinal stromal tumour. |
| New listing (Major submission) | RISDIPLAM Powder for oral solution 0.75 mg per 1 mL, 80 mLEvrysdi®Roche Products Pty Ltd | Spinal muscular atrophy | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of spinal muscular atrophy. |
| New listing (Major submission)WITHDRAWN | ROXADUSTATTablet 20 mgTablet 50 mgTablet 70 mgTablet 100 mgEvrenzo®AstraZeneca Pty Ltd | Anaemia associated with chronic kidney disease | To request an Authority Required (STREAMLINED) listing for the treatment of anaemia associated with chronic kidney disease. |
| Change to listing(Major submission) | SEMAGLUTIDE Solution for injection 2 mg in 1.5 mL pre-filled penSolution for injection 4 mg in 3 mL pre-filled penOzempic®Novo Nordisk Pharmaceuticals Pty Ltd | Type 2 diabetes mellitus (T2DM) | To request an Authority Required (STREAMLINED) listing for the treatment of T2DM. |
| New listing (Major submission) | TAFAMIDIS Capsule 61 mgVyndamax®Pfizer Australia Pty Ltd | Transthyretin cardiac amyloidosis | To request an Authority Required (Written) listing for the treatment of transthyretin cardiac amyloidosis. |
| Change listing(Minor submission) | TEDUGLUTIDEPowder for injection 5 mg with diluentRevestive®Takeda Pharmaceuticals Australia Pty Ltd | Short bowel syndrome (SBS)  | To extend the Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing to include paediatric patients with SBS.  |
| Change to listing(Minor submission) | TERIPARATIDEInjection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled cartridgeTerrosaGedeon Richter Australia Pty Ltd | Severe established osteoporosis | To request Authority Required (STREAMLINED) listing of teriparatide biosimilar under the same conditions as its reference biologic.  |
| Change to listing (Minor submission) | TESTOSTERONE Transdermal cream 50 mg per mL, 50 mLAndroForte® 5Lawley Pharmaceuticals Pty Ltd | Testosterone deficiency | To request a change in the number of repeats for the currently listed testosterone cream. |
| Change to listing(Minor submission) | TETRACOSACTIDECompound depot injection 1 mg in 1 mLSynacthen® Depot 1 mg/1 mLClinect Pty Ltd | Hypsarrhythmia and/or infantile spasms | To request a change in restriction level from Restricted Benefit to Unrestricted Benefit listing.  |
| New listing (Major submission) | TUCATINIBTablet 150 mgTablet 50 mgTukysa®Lucid Health Consulting Pty Ltd | Breast cancer | To request an Authority Required (Telephone) listing for the treatment of metastatic (Stage IV) human epidermal growth factor receptor 2 (HER2) positive breast cancer. |
| Change to listing(Major submission) | UPADACITINIB Tablet 15 mgRinvoq®Abbvie Pty Ltd | Ankylosing spondylitis | To request an Authority Required (Written) listing for the treatment of ankylosing spondylitis. |
| Change to listing(Major submission) | UPADACITINIB Tablet 15 mgRinvoq®Abbvie Pty Ltd | Psoriatic arthritis | To request an Authority Required (Written) listing for the treatment of severe psoriatic arthritis. |
| Change to listing(Major submission) | USTEKINUMABInjection 45 mg in 0.5 mLStelara®Janssen-Cilag Pty Ltd | Plaque psoriasis | To request an Authority Required (Written) listing for the treatment of paediatric patients with severe chronic plaque psoriasis. |
| Change to listing(Major submission) | VENETOCLAX Tablet 100 mgVenclexta®Abbvie Pty Ltd | Acute myeloid leukaemia (AML) | To request an Authority Required (Telephone/Online) listing for the treatment of AML. |
| Subcommittee report (DUSC Analysis)  | Nusinersen Spinraza®Biogen Australia Pty Ltd  | Spinal muscular atrophy (SMA)  | To compare the predicted and actual utilisation of nusinersen for the treatment of SMA since PBS listing.  |
| Subcommittee report (DUSC Analysis)  | Ocular lubricants All brands and strengths Various sponsors  | Severe dry eye syndrome  | To assess the utilisation of PBS listed ocular lubricants for severe dry eye syndrome.  |