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| The PBAC agenda primarily consists of applications relating to the new listing of a drug or vaccine on the Pharmaceutical Benefits Scheme (PBS) or the National Immunisation Program (NIP).The PBAC agenda consists of the following:**1 Minutes of Previous Meeting****2 Chair’s report (verbal)****3 Matters arising from the minutes** **4 Matters arising/outstanding****5 New listing 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****16 Delistings****17 Positive recommendations not accepted by applicants after 2 years**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 Services Australia or the DVA but require the recording of a streamlined authority code (noted as Authority required (STREAMLINED)).

Initial submissions are categorised broadly as:* *Category 1 or 2:* Submissions to list new medicines on the Schedule of Pharmaceutical Benefits or to make substantial changes to current listings are generally classified as Category 1 or 2 submissions. These submissions require presentation of an economic evaluation.
* *Category 3 or 4:* 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 Category 3 or 4 submissions. These submissions do not usually require the presentation of an economic evaluation.

Resubmissions are categorised broadly as Standard Re-entry Pathway, Early Resolution Pathway, Early Re-entry Pathway or Facilitated Resolution Pathway. Submission categories and resubmission pathways are outlined in the [Procedure Guidance](https://www.pbs.gov.au/info/industry/listing/listing-steps). The PBAC meeting agenda will be published in week 3 – and updated in week 8 (to include early pathway resubmissions, and items for review under the process for reviewing positive PBS-listing recommendations not accepted by applicants) in each PBAC cycle as per [PBS Calendar](https://www.pbs.gov.au/info/industry/useful-resources/pbs-calendar).  |

| **Drug Name, form(s), strength(s) and Sponsor, Submission type**(Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing) | **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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| ABROCITINIBTablet 50 mgTablet 100 mgTablet 200 mgCibinqo®PFIZER AUSTRALIA PTY LTD(New PBS listing) | Severe atopic dermatitis | To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of severe atopic dermatitis. |
| AFLIBERCEPTSolution for intravitreal injection 11.34 mg in 100 microlitres (114.3 mg per mL) pre-filled syringeEylea®BAYER AUSTRALIA LTD(New PBS listing) | Diabetic macular oedema (DMO) | To request a General Schedule Authority Required (Written) listing of a new form for the initial treatment and an Authority Required (STREAMLINED) listing for the continuing treatment of DMO. |
| AFLIBERCEPTSolution for intravitreal injection 11.34 mg in 100 microlitres (114.3 mg per mL) pre-filled syringeEylea®BAYER AUSTRALIA LTD(New PBS listing) | Subfoveal choroidal neovascularisation (CNV) secondary to age-related macular degeneration (AMD) | To request a General Schedule Authority Required (Written) listing of a new form for the initial treatment and an Authority Required (STREAMLINED) listing for the continuing treatment of subfoveal CNV due to AMD. |
| AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS AND MINERALS WITHOUT PHENYLALANINETablets (modified release), 54 g protein per 100 g, 100 g, pack of 6 (PKU Easy Microtabs Plus)PKU Easy Microtabs PlusORPHARMA PTY LTD(New PBS listing) | Phenylketonuria (PKU) | To request a General Schedule Restricted Benefit listing for the dietary management of phenylketonuria. |
| AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDESOral powder 400 g (Essential Care Jr)Essential Care JrCORTEX HEALTH PTY LTD(New PBS listing) | Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulaeSevere intestinal malabsorption including short bowel syndromeEosinophilic oesophagitisCows' milk protein enteropathySevere cows' milk protein enteropathy with failure to thriveProven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy proteinCows' milk anaphylaxis | To request a General Schedule Authority Required (Telephone/Online) listing of a new pack size with new formulation for the same indications as the current listing.  |
| AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHANSachets containing oral powder 12.5 g, pack of 30 (GA explore5)GA explore5™VITAFLO AUSTRALIA PTY LIMITED(New PBS listing) | Glutaric aciduria type 1Pyridoxine dependent epilepsy | To request a General Schedule Restricted Benefit listing for the dietary management of proven glutaric aciduria type 1 and pyridoxine dependent epilepsy. |
| AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE, THREONINE AND VALINE AND LOW IN ISOLEUCINESachets containing oral powder 12.5 g, pack of 30 (MMA/PA explore5)MMA/PA explore5™VITAFLO AUSTRALIA PTY LIMITED(New PBS listing) | Methylmalonic acidaemiaPropionic acidaemia | To request a General Schedule Restricted Benefit listing for the dietary management of methylmalonic acidaemia and propionic acidaemia. |
| AMIVANTAMABSolution concentrate for I.V. infusion 350 mg in 7 mLRybrevant®JANSSEN-CILAG PTY LTD(New PBS listing) | Non-small cell lung cancer (NSCLC) | To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for the treatment of epidermal growth factor receptor exon 20 insertion mutation-positive locally advanced or metastatic (Stage IIIb-IV) NSCLC in treatment naive patients. |
| BUDESONIDESuppository 4 mgBudenofalk®DR FALK PHARMA AUSTRALIA PTY LTD(New PBS listing) | Ulcerative colitis | To request a General Schedule Unrestricted Benefit listing of a new form for the short-term treatment of mild to moderate ulcerative colitis limited to the rectum. |
| CAPIVASERTIBTablet 160 mgTablet 200 mgTruqap®ASTRAZENECA PTY LTD(New PBS listing) | Hormone receptor-positive (HR+) human epidermal growth factor receptor 2-negative (HER2-) locally advanced (unresectable) or metastatic breast cancer | To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of HR+/HER2- locally advanced unresectable or metastatic breast cancer with evidence of a serine/threonine protein kinase (AKT) pathway alteration, following recurrence or progression on or after endocrine therapy. |
| CLOBETASOLCream containing clobetasol propionate 500 micrograms per g, 30 gOintment containing clobetasol propionate 500 micrograms per g, 30 gXobet®ARROTEX PHARMACEUTICALS PTY LTD(New PBS listing) | Corticosteroid responsive dermatoses | To request a General Schedule Restricted Benefit listing for the treatment of corticosteroid responsive dermatoses. |
| DENOSUMABInjection 60 mg in 1 mL pre-filled syringeJubbonti®Injection 120 mg in 1.7 mLWyost®SANDOZ PTY LTD(New PBS listing) | OsteoporosisGiant cell tumour of boneBone metastases | To request General Schedule Authority Required (STREAMLINED) listings of denosumab biosimilars under the same conditions as their respective reference biologics. |
| DROSPIRENONEPack containing 24 tablets 4 mg and 4 inert tabletsSlinda®BESINS HEALTHCARE AUSTRALIA PTY LTD(New PBS listing) | Contraception | To request a General Schedule unrestricted benefit listing.  |
| DURVALUMABSolution concentrate for I.V. infusion 120 mg in 2.4 mLSolution concentrate for I.V. infusion 500 mg in 10 mLImfinzi®OLAPARIBTablet 100 mgTablet 150 mgLynparza®ASTRAZENECA PTY LTD(Change to existing listing) | Advanced, metastatic or recurrent endometrial cancer | To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing of durvalumab in combination with platinum-based chemotherapy, followed by maintenance treatment with or without olaparib, for the treatment of advanced, metastatic or recurrent endometrial cancer. |
| ENFORTUMAB VEDOTINPowder for I.V. infusion 20 mgPowder for I.V. infusion 30 mgPadcev®ASTELLAS PHARMA AUSTRALIA PTY LTD(Change to existing listing) | Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer (la/mUC) | To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first line treatment of la/mUC in combination with pembrolizumab. |
| ENZALUTAMIDECapsule 40 mgXtandi®ASTELLAS PHARMA AUSTRALIA PTY LTD(Change to existing listing) | Non-metastatic hormone-sensitive prostate cancer (m0HSPC) | To request a General Schedule Authority Required (Telephone/Online) for the treatment of m0HSPC with or without concurrent treatment with androgen deprivation therapy. |
| EPCORITAMABSolution concentrate for subcutaneous injection 4 mg in 0.8 mLSolution for subcutaneous injection 48 mg in 0.8 mLEpkinly®ABBVIE PTY LTD(New PBS listing) | Relapsed or refractory diffuse large B-cell lymphoma (RR DLBCL) | To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of RR DLBCL. |
| ERENUMABSolution for subcutaneous injection 70 mg in 1 mL single dose pre-filled penSolution for subcutaneous injection 140 mg in 1 mL single dose pre-filled penAimovig®NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED(New PBS listing) | Chronic migraine | Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the prophylaxis of adults with chronic migraine who have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications. |
| ESTRADIOL AND PROGESTERONEPack containing transdermal gel (pump pack) estradiol 750 micrograms (as hemihydrate) per 1.25 g dose, 64 doses and 30 capsules progesterone 100 mg (micronised)Estrogel® ProBESINS HEALTHCARE AUSTRALIA PTY LTD(New PBS listing) | Menopausal hormone therapy | To request a General Schedule unrestricted benefit listing. |
| ESTRADIOLTransdermal gel (pump pack) 750 micrograms (as hemihydrate) per 1.25 g dose, 64 dosesEstrogel®BESINS HEALTHCARE AUSTRALIA PTY LTD(New PBS listing) | Menopausal hormone therapy | To request a General Schedule unrestricted benefit listing. |
| FENFLURAMINEOral solution 2.2 mg (as hydrochloride) per mL, 360 mLFintepla®UCB AUSTRALIA PROPRIETARY LIMITED(New PBS listing) | Seizures associated with Dravet Syndrome | To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of seizures associated with Dravet Syndrome. |
| FINGOLIMODCapsule 250 micrograms (as hydrochloride)Capsule 500 micrograms (as hydrochloride)Gilenya®OFATUMUMABSolution for injection 20 mg in 0.4 mL pre‑filled penKesimpta®SIPONIMOD Tablet 250 micrograms (as hemifumarate)Tablet 2 mg (as hemifumarate)Mayzent®NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED(Change to existing listing) | Multiple sclerosis (MS) | To request an amendment to the listings for the treatment of MS to allow prescribing by nurse practitioners. |
| FOLLITROPIN ALFA WITH LUTROPIN ALFAInjection 900 I.U. - 450 I.U. in 1.44 mL multi‑dose cartridgePergoveris®MERCK HEALTHCARE PTY LTD(Change to existing listing) | Stimulation of follicular development | To request an amendment to the existing Section 100 (In Vitro Fertilisation Program) Authority Required (STREAMLINED) listing for the stimulation of follicular development to remove the requirement for titration of separate follicular stimulating hormone and luteinising hormone therapies after at least one cycle of treatment, and to request an increase to the maximum quantity. |
| FOSLEVODOPA WITH FOSCARBIDOPASolution for subcutaneous infusion foslevodopa 2400 mg with foscarbidopa 120 mg in 10 mLVyalev®ABBVIE PTY LTD(New PBS listing) | Advanced Parkinson disease | Resubmission to request General Schedule and Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listings for the treatment of advanced Parkinson disease with severe disabling motor fluctuations not adequately controlled by oral therapy. |
| GARADACIMABInjection 200 mg in 1.2 mL pre-filled penTBDCSL BEHRING (AUSTRALIA) PTY LTD(New PBS listing) | Hereditary angioedema (HAE) | To request a General Schedule Authority Required (Written) listing for the initial treatment and an Authority Required (Telephone/Online) listing for the continuing treatment of HAE. |
| GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALSSachets containing oral powder 15 g, 30 (PKU Build 10)PKU Build 10CORTEX HEALTH PTY LTD(New PBS listing) | Phenylketonuria (PKU) | To request a General Schedule Restricted Benefit listing of a new pack size for the dietary management of phenylketonuria.  |
| INCLISIRANInjection 284 mg in 1.5 mL single use pre-filled syringeLeqvio®NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED(Change to existing listing) | Non-familial hypercholesterolaemiaFamilial heterozygous hypercholesterolaemia | To request an amendment to the restriction level from Authority Required (Telephone/Online) to Authority Required (STREAMLINED) for the initial treatment of familial heterozygous hypercholesterolaemia and non-familial hypercholesterolaemia. |
| INCLISIRANInjection 284 mg in 1.5 mL single use pre-filled syringeLeqvio®NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED(Change to existing listing) | Non-familial hypercholesterolaemiaFamilial heterozygous hypercholesterolaemia | To request an amendment to the listing for the treatment of familial heterozygous hypercholesterolaemia and non-familial hypercholesterolaemia to allow prescribing by nurse practitioners. |
| INCOBOTULINUMTOXINALyophilised powder for injection 100 unitsXeomin®MERZ AUSTRALIA PTY LTD(Change to existing listing) | Chronic sialorrhea | To request a Section 100 (Botulinum Toxin Program) Authority Required (STREAMLINED) listing for the treatment of chronic sialorrhea due to neurological disorders. |
| INCOBOTULINUMTOXINALyophilised powder for injection 100 unitsXeomin®MERZ AUSTRALIA PTY LTD(Change to existing listing)WITHDRAWN | Moderate to severe spasticity of the upper limbDynamic equinus foot deformity | To request a Section 100 (Botulinum Toxin Program) Authority Required (STREAMLINED) listing for the treatment of moderate to severe spasticity of the upper limb and dynamic equinus foot deformity in patients with cerebral palsy aged 2 to 17 years.  |
| IRINOTECANSolution for I.V. infusion containing nanoliposomal irinotecan (as sucrosofate) 43 mg in 10 mLOnivyde®SERVIER LABORATORIES (AUST.) PTY. LTD.(New PBS listing) | Metastatic pancreatic adenocarcinoma (mPAC) | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing, for use in combination with oxaliplatin, 5-fluorouracil and folinic acid, for the first-line treatment of mPAC. |
| IVOSIDENIBTablet 250 mgTibsovo®SERVIER LABORATORIES (AUST.) PTY.LTD.(New PBS listing) | Bile duct cancer(cholangiocarcinoma) | Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma who have previously progressed on chemotherapy and have a confirmed *IDH1* mutation. |
| LANADELUMABInjection 150 mg in 1 mL single use pre-filled syringeTakhzyro®TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD.(New PBS listing) | Hereditary angioedema (HAE) | To request a General Schedule Authority Required (Written) listing of a new form for the treatment of HAE Types 1 or 2 in patients aged 2 to 11 years. |
| LEUPRORELINSuspension for subcutaneous injection (modified release) containing leuprorelin acetate 7.5 mg, injection setSuspension for subcutaneous injection (modified release) containing leuprorelin acetate 22.5 mg, injection setSuspension for subcutaneous injection (modified release) containing leuprorelin acetate 30 mg, injection setSuspension for subcutaneous injection (modified release) containing leuprorelin acetate 45 mg, injection setEligard®MUNDIPHARMA PTY LIMITED(Change to existing listing) | Central precocious pubertyLocally advanced (stage C) or metastatic (stage D) carcinoma of the prostate | To request a modified injection device for the existing listing. |
| MACITENTAN WITH TADALAFILTablet containing macitentan 10 mg with tadalafil 40 mgOpsynvi®JANSSEN-CILAG PTY LTD(New PBS listing) | Pulmonary arterial hypertension (PAH) | To request a Section 100 (Highly Specialised Drug Program) Authority Required (Written) listing for the continuing treatment of PAH in patients who are on stable doses of macitentan and tadalafil as combination therapy. |
| MARIBAVIRTablet 200 mgLivtencity®TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD.(New PBS listing) | Post-transplant cytomegalovirus (CMV) | Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for treatment of post-transplant CMV infection and disease that is refractory, resistant or intolerant to one or more prior therapies. |
| MOMELOTINIBTablet 100 mg (as dihydrochloride monohydrate)Tablet 150 mg (as dihydrochloride monohydrate)Tablet 200 mg (as dihydrochloride monohydrate)Omjjara®GLAXOSMITHKLINE AUSTRALIA PTY LTD(New PBS listing) | Myelofibrosis with moderate to severe anaemia | To request a General Schedule Authority Required (Telephone/Online) listing for initial treatment and an Authority Required (STREAMLINED) listing for continuing treatment of intermediate or high-risk primary myelofibrosis, post-polycythaemia vera myelofibrosis or post-essential thrombocythaemia myelofibrosis in patients with moderate to severe anaemia and who are Janus kinase (JAK) inhibitor naïve or have been treated with ruxolitinib. |
| NINTEDANIBCapsule 100 mgCapsule 150 mgOfev®BOEHRINGER INGELHEIM PTY LTD(Change to existing listing) | Idiopathic pulmonary fibrosis (IPF)Progressive fibrosing Interstitial lung disease (PF-ILD) | To request the PBAC consider the combined utilisation and financial estimates for the IPF and PF-ILD indications of nintedanib listed on the PBS. |
| 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(Change to existing listing)TO BE CONSIDERED AT A FUTURE PBAC MEETING  | Non-small cell lung cancer (NSCLC) | To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the perioperative treatment of NSCLC. |
| 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(Change to existing listing) | Urothelial carcinoma (UC) | To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for the first-line treatment of cisplatin-eligible adult patients with unresectable or metastatic UC. |
| OLAPARIBTablet 100 mgTablet 150 mgLynparza®ASTRAZENECA PTY LTD(New PBS listing) | Metastatic castration-resistant prostate cancer (mCRPC) | Resubmission to request a General Schedule Authority Required (Telephone/Online) listing for the first line treatment of mCRPC in patients with a Class 4 or 5 Breast Cancer Gene 1 (*BRCA1*) or *BRCA2* mutation who have not received prior treatment with a novel hormonal agent. |
| PALOVAROTENECapsule 1 mgCapsule 1.5 mgCapsule 2.5 mgCapsule 5 mgCapsule 10 mgSohonos®IPSEN PTY LTD(New PBS listing) | Fibrodysplasia Ossificans Progressiva (FOP) | To request a General Schedule Authority Required (Written) listing for chronic treatment of FOP and an Authority Required (STREAMLINED) listing for flare‑up treatment of FOP. |
| PEMBROLIZUMABSolution concentrate for I.V. infusion 100 mg in 4 mLKeytruda®MERCK SHARP & DOHME (AUSTRALIA) PTY LTD(Change to existing listing) | Renal cell carcinoma (RCC) | To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the adjuvant treatment of clear cell RCC at intermediate-high or high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions. |
| PNEUMOCOCCAL (CONJUGATE, 21‑VALENT) VACCINEInjection (0.5 mL)Capvaxive®MERCK SHARP & DOHME (AUSTRALIA) PTY LTD(New NIP listing)WITHDRAWN | Prevention of pneumococcal disease | To request a National Immunisation Program listing for the prevention of pneumococcal disease in adults.  |
| PROGESTERONECapsule 100 mgPrometrium®BESINS HEALTHCARE AUSTRALIA PTY LTD(New PBS listing) | Menopausal hormone therapy | To request a General Schedule unrestricted benefit listing. |
| RAVULIZUMABSolution concentrate for I.V. infusion 300 mg in 3 mLSolution concentrate for I.V. infusion 1,100 mg in 11 mLUltomiris®ALEXION PHARMACEUTICALS AUSTRALASIA PTY LTD(Change to existing listing) | Neuromyelitis Optica Spectrum Disorder (NMOSD) | To request a Section 100 (Highly Specialised Drug Program) Authority Required (Written) listing for the treatment of adult patients with NMOSD. |
| RELUGOLIX WITH ESTRADIOL AND WITH NORETHISTERONE ACETATETablet containing relugolix 40 mg with estradiol (as hemihydrate) 1 mg and with norethisterone acetate 0.5 mgRyeqo®GEDEON RICHTER AUSTRALIA PTY LTD(New PBS listing) | Endometriosis | To request reconsideration of the utilisation and financial estimates of the General Schedule Authority Required (STREAMLINED) listing for the treatment of moderate to severe pain associated with endometriosis. |
| RESPIRATORY SYNCYTIAL VIRUS VACCINEInjection (0.5 mL)Abrysvo®PFIZER AUSTRALIA PTY LTD(New NIP listing) | Respiratory syncytial virus (RSV) | To request a National Immunisation Program listing for the prevention of RSV lower respiratory tract disease in individuals 60 years of age and above who meet certain criteria. |
| RIBOCICLIBTablet 200 mgKisqali®NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED(Change to existing listing) | Hormone receptor-positive (HR+) human epidermal growth factor receptor 2-negative (HER2-) breast cancer | To request a General Schedule Authority Required (Telephone/Online) listing for the adjuvant treatment of HR+/HER2- lymph node positive, invasive, resected early breast cancer at high risk of disease recurrence. |
| RIVAROXABANTablet 2.5 mgTablet 10 mgXarelto®ALPHAPHARM PTY LTD(New PBS listing) | Prevention of venous thromboembolismChronic stable atherosclerotic disease | To request General Schedule Authority Required (STREAMLINED) listings of new pack sizes with amended maximum quantities and number of repeats for the treatment of chronic stable atherosclerotic disease and the prevention of recurrent venous thromboembolism. |
| SACUBITRIL WITH VALSARTANTablet containing sacubitril 24.3 mg with valsartan 25.7 mgTablet containing sacubitril 48.6 mg with valsartan 51.4 mgTablet containing sacubitril 97.2 mg with valsartan 102.8 mgEntresto®NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED(Change to existing listing) | Chronic heart failure | To request an amendment to the General Schedule Authority Required (STREAMLINED) listings for the treatment of chronic heart failure to allow treatment initiation by nurse practitioners. |
| SEMAGLUTIDESolution for injection 2 mg in 3 mL pre-filled penOzempic®NOVO NORDISK PHARMACEUTICALS PTY. LIMITED(New PBS listing) | Diabetes mellitus type 2 (T2DM) | To request a General Schedule Authority Required (Telephone/Online) listing of a new strength for the initial treatment and an Authority Required (STREAMLINED) listing for the continuing treatment of T2DM. |
| TIOTROPIUM WITH OLODATEROLSolution for oral inhalation containing tiotropium 2.5 micrograms (as bromide monohydrate) with olodaterol 2.5 micrograms (as hydrochloride) per dose, 60 doses, pack of 2Spiolto® Respimat®BOEHRINGER INGELHEIM PTY LTD(New PBS listing) | Chronic obstructive pulmonary disease (COPD) | To request listing of a new pack size for 60-day prescribing for the treatment of COPD. |
| TIOTROPIUMSolution for oral inhalation 2.5 micrograms (as bromide monohydrate) per actuation (2 x 60 actuations), pack of 2Spiriva® Respimat®BOEHRINGER INGELHEIM PTY LTD(New PBS listing) | Severe asthmaBronchospasm and dyspnoea associated with chronic obstructive pulmonary disease (COPD) | To request listing of a new pack size for 60-day prescribing for the treatment of severe asthma and for bronchospasm and dyspnoea associated with COPD. |
| TIRZEPATIDESolution for injection 2.5 mg in 0.5 mL vial/pre‑filled penSolution for injection 5 mg in 0.5 mL vial/pre‑filled penSolution for injection 7.5 mg in 0.5 mL vial/pre‑filled penSolution for injection 10 mg in 0.5 mL vial/pre‑filled penSolution for injection 12.5 mg in 0.5 mL vial/pre‑filled penSolution for injection 15 mg in 0.5 mL vial/pre‑filled penMounjaro®Injection 4.17 milligrams per mL (2.5 mg per dose) in multi-dose pre-filled pen, 4 dosesInjection 8.33 milligrams per mL (5 mg per dose) in multi-dose pre-filled pen, 4 dosesInjection 12.5 milligrams per mL (7.5 mg per dose) in multi-dose pre-filled pen, 4 dosesInjection 16.67 milligrams per mL (10 mg per dose) in multi-dose pre-filled pen, 4 dosesInjection 20.83 milligrams per mL (12.5 mg per dose) in multi-dose pre-filled pen, 4 dosesInjection 25 milligrams per mL (15 mg per dose) in multi-dose pre-filled pen, 4 dosesMounjaro® KwikPen®ELI LILLY AUSTRALIA PTY LTD(New PBS listing) | Diabetes mellitus type 2 (T2DM) | Resubmission to request a General Schedule Authority Required (Written) listing as dual therapy in combination with metformin for the treatment of adult patients with inadequately controlled T2DM who (i) have comorbid severe obesity or (ii) identify as Aboriginal and Torres Strait Islander. |
| TISLELIZUMABSolution concentrate for I.V. infusion 100 mg in 10 mLTevimbra®BEIGENE AUS PTY LTD(New PBS listing) | Oesophageal squamous cell carcinoma (OSCC) | To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first line treatment of patients with unresectable advanced, recurrent, or metastatic OSCC. |
| TRIGLYCERIDES, LONG CHAIN WITH GLUCOSE POLYMEROral liquid 1 L, 6 (ProZero)ProZero®VITAFLO AUSTRALIA PTY LIMITED(Change to existing listing) | Proven inborn errors of protein metabolism | To request an amendment to the restriction level from Restricted Benefit to Authority Required (STREAMLINED) for the treatment of proven inborn errors of protein metabolism. The submission also requested amendments to the clinical criteria.  |
| USTEKINUMABInjection 45 mg in 0.5 mL single use pre-filled syringeInjection 90 mg in 1 mL single use pre-filled syringeSolution for I.V. infusion 130 mg in 26 mLSteqeyma®CELLTRION HEALTHCARE AUSTRALIA PTY LTD(New PBS listing) | Severe chronic plaque psoriasisSevere psoriatic arthritisSevere Crohn diseaseComplex refractory fistulising Crohn disease | To request General Schedule and Section 100 (Highly Specialised Drugs Program) listings of an ustekinumab biosimilar for the treatment of severe chronic plaque psoriasis, severe psoriatic arthritis, severe Crohn disease, and complex refractory fistulising Crohn disease. |
| VUTRISIRANInjection 25 mg (as sodium) in 0.5 mL pre‑filled syringeAmvuttra®MEDISON PHARMA AUSTRALIA PTY LIMITED(New PBS listing) | Hereditary transthyretin-mediated (hATTR) amyloidosis | To request a General Schedule Authority Required (Written) listing for the treatment of hATTR amyloidosis in adult patients with stage 1 or stage 2 polyneuropathy. |
| DASATINIBTablet 20 mgTablet 50 mgTablet 70 mgTablet 100 mgAll BrandsNILOTINIBCapsule 150 mgCapsule 200 mgTasigna®NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED(Sub-committee report DUSC analysis) | Chronic myeloid leukaemia (CML) | To assess the utilisation of PBS listed dasatinib and nilotinib for the treatment of CML. |
| IDELALISIBTablet 100 mgTablet 150 mgZydelig®GILEAD SCIENCES PTY LIMITED(Sub-committee report DUSC analysis) | Refractory follicular B-cell non-Hodgkin lymphoma | To assess the utilisation of PBS listed idelalisib for the treatment of refractory follicular B-cell non-Hodgkin lymphoma. |
| MOLNUPIRAVIRCapsule 200 mgLagevrio®MERCK SHARP & DOHME (AUSTRALIA) PTY LTD (Sub-committee report DUSC analysis) | Severe-acute-respiratory-syndrome coronavirus-2 (SARS-CoV-2) infection | To assess the utilisation of PBS listed molnupiravir for the treatment of SARS- CoV-2 infection. |
| DUPILUMABInjection 300 mg in 2 mL single dose autoinjectorInjection 200 mg in 1.14 mL single dose autoinjector Dupixent® SANOFI-AVENTIS AUSTRALIA PTY LTD(Review of positive PBAC recommendations not accepted by applicants) | Chronic severe atopic dermatitisUncontrolled severe asthma | To request the PBAC review its November 2022 recommendation that has not yet been accepted by the applicant.  |
| ETANERCEPT Injection 50 mg in 1 mL single use auto‑injector, 4 Nepexto® ALPHAPHARM PTY LTD(Review of positive PBAC recommendations not accepted by applicants) | Rheumatoid arthritisJuvenile idiopathic arthritisPsoriatic arthritisPlaque psoriasisAnkylosing spondylitis | To request the PBAC review its November 2022 recommendation that has not yet been accepted by the applicant.  |
| HYDROCORTISONE Capsule containing granules 0.5 mg Capsule containing granules 1 mg Capsule containing granules 2 mg Capsule containing granules 5 mg Alkindi® CHIESI AUSTRALIA PTY LTD(Review of positive PBAC recommendations not accepted by applicants) | Adrenal insufficiency | To request the PBAC review its July 2021 recommendation that has not yet been accepted by the applicant.  |
| INFLIXIMABSolution for injection 120 mg in 1 mL pre‑filled pen Solution for injection 120 mg in 1 mL pre‑filled syringe Remsima® SC CELLTRION HEALTHCARE AUSTRALIAPTY LTD(Review of positive PBAC recommendations not accepted by applicants) | Rheumatoid arthritis  | To request the PBAC review its November 2022 recommendation that has not yet been accepted by the applicant.  |
| INSULIN ASPART Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5Truvelog®Injections (human analogue), prefilled pen, 100 units per mL, 3 mL, 5Truvelog® Solostar SANOFI-AVENTIS AUSTRALIA PTY LTD(Review of positive PBAC recommendations not accepted by applicants) | Diabetes mellitus | To request the PBAC review its November 2021 recommendation that has not yet been accepted by the applicant.  |
| RISANKIZUMABSolution concentrate for I.V. infusion 600 mg in 10 mL Injection 360 mg in 2.4 mL in prefilled cartridge Skyrizi® ABBVIE PTY LTD(Review of positive PBAC recommendations not accepted by applicants) | Crohn disease | To request the PBAC review its November 2022 recommendation that has not yet been accepted by the applicant.  |
| Review of PBS items for Nurse Practitioner prescribing subject to a ‘Continuing Therapy Only’ administrative noteVarious forms and strengthsVarious brandsVarious sponsors(Other matters) | Various | To request the PBAC consider a list of medicines with a Continuing Therapy Only (CTO) administrative note for nurse practitioner prescribing, and seek PBAC advice on whether the CTO note continues to be appropriate for specific listings.  |

Version 6

Items added or amended

1. PNEUMOCOCCAL (CONJUGATE, 21-VALENT) VACCINE (Capvaxive®) – Withdrawn
2. NIVOLUMAB (Opdivo®) non-small cell lung cancer – To be considered at a future PBAC Meeting

Items added or amended previously

1. INCOBOTULINUMTOXINA (Xeomin®) – Withdrawn
2. NIVOLUMAB (Opdivo®) non-small cell lung cancer – Form(s) amended
3. NIVOLUMAB (Opdivo®) urothelial carcinoma – Form(s) amended
4. RIVAROXABAN (Xarelto®) – Sponsor amended
5. CAPIVASERTIB (Truqap®) – Purpose of submission amended
6. FOSLEVODOPA WITH FOSCARBIDOPA (Vyalev®) – Added
7. GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS (PKU Build 10) – Form amended
8. IVOSIDENIB (Tibsovo®) – Added
9. SEMAGLUTIDE (Ozempic®) – Purpose of submission amended
10. TIRZEPATIDE (Mounjaro®; Mounjaro® KwikPen®) – Forms, strength, trade name and purpose of submission amended
11. DUPILUMAB (Dupixent®) – Review of positive PBAC recommendations not accepted by applicants – Added
12. ETANERCEPT (Nepexto®) – Review of positive PBAC recommendations not accepted by applicants – Added
13. HYDROCORTISONE (Alkindi®) – Review of positive PBAC recommendations not accepted by applicants – Added
14. INFLIXIMAB (Remsima® SC) – Review of positive PBAC recommendations not accepted by applicants – Added
15. INSULIN ASPART (Truvelog®; Truvelog® Solostar) – Review of positive PBAC recommendations not accepted by applicants – Added
16. RISANKIZUMAB (Skyrizi®) – Review of positive PBAC recommendations not accepted by applicants – Added
17. Review of PBS items for Nurse Practitioner prescribing subject to a ‘Continuing Therapy Only’ administrative note (Various brands) – Added
18. ERENUMAB (Aimovig®) – Purpose of submission amended
19. FENFLURAMINE (Fintepla®) – Drug type and use and purpose of submission amended