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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.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 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****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.) |
| --- | --- | --- |
| ADALIMUMABInjection 20 mg in 0.2 mL pre-filled syringeInjection 40 mg in 0.4 mL pre-filled syringeInjection 40 mg in 0.4 mL pre-filled penInjection 80 mg 0.8 mL pre-filled syringeInjection 80 mg in 0.8 mL pre-filled penHyrimoz®SANDOZ PTY LTD(New PBS listing) | Severe Crohn disease (CD)Moderate to severe ulcerative colitis (UC)Severe active juvenile idiopathic arthritis (JIA)Complex refractory fistulising Crohn disease (CD)Severe active rheumatoid arthritis (RA)Severe psoriatic arthritis (PsA)Ankylosing spondylitis (AS)Severe chronic plaque psoriasis (CPP)Moderate to severe hidradenitis suppurativa (HS) | To request General Schedule and Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listings for initial treatment and Authority Required (STREAMLINED) listings for subsequent continuing treatment of new forms of an existing biosimilar under the same conditions as the currently listed forms and strengths as its reference biologic. |
| ADRENALINE (EPINEPHRINE)I.M. injection 150 micrograms in 0.15 mL (as acid tartrate) single dose syringe auto injectorI.M. injection 300 micrograms in 0.3 mL (as acid tartrate) single dose syringe auto injectorJext® JnrJext®HEALTH TECHNOLOGY ANALYSTS PTY LIMITED(New PBS listing) | Acute allergic reaction with anaphylaxis | To request a General Schedule Authority Required (Telephone/Online) listing of a new form for the treatment of acute allergic reaction with anaphylaxis. |
| APALUTAMIDETablet 240 mgErlyand®JANSSEN-CILAG PTY LTD(New PBS listing) | Non-metastatic castration-resistant carcinoma of the prostateMetastatic castration-sensitive carcinoma of the prostate | To request a General Schedule Authority Required (Telephone/Online) listing of a new strength for the treatment of non-metastatic castration-resistant and metastatic castration-sensitive carcinoma of the prostate. |
| ARIPIPRAZOLEI.M. injection (modified release) 720 mg in 2.4 mL pre-filled syringeI.M. injection (modified release) 960 mg in 3.2 mL pre-filled syringeAbilify Asimtufii®LUNDBECK AUSTRALIA PTY LTD(New PBS listing)TO BE CONSIDERED AT A FUTURE PBAC MEETING | Schizophrenia | To request a General Schedule Authority Required (STREAMLINED) listing of new forms for the maintenance treatment of schizophrenia. |
| BELZUTIFANTablet 40 mgWelireg®MERCK SHARP & DOHME (AUSTRALIA) PTY LIMITED(New PBS listing) | Von Hippel-Lindau (VHL) disease  | To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of patients with VHL disease who require therapy for associated renal cell carcinoma, central nervous system haemangioblastomas, or pancreatic neuroendocrine tumours, not requiring immediate surgery.  |
| BLINATUMOMABPowder for I.V. infusion 38.5 microgramsBlincyto®AMGEN AUSTRALIA PTY LIMITED(Change to existing listing) | Measurable residual disease (MRD)-negative B-cell precursor acute lymphoblastic leukaemia (B-ALL) | To request a Section 100 (Efficient Funding of Chemotherapy) listing for the treatment of newly diagnosed B-ALL in patients who are MRD-negative after initial induction chemotherapy. |
| DIENOGEST Tablet 2 mgVisanne®BAYER AUSTRALIA LTD(New PBS listing) | Endometriosis | To request a General Schedule Restricted Benefit listing for the treatment of endometriosis. |
| DROSPIRENONE WITH ETHINYLESTRADIOL Pack containing 24 tablets 3 mg drospirenone with 20 micrograms ethinylestradiol (as betadex clathrate) and 4 inert tabletsYaz®Pack containing 21 tablets 3 mg drospirenone with 30 micrograms ethinylestradiol and 7 inert tabletsYasmin®BAYER AUSTRALIA LTD(New PBS listing) | Oral contraceptiveModerate acne vulgaris in women who seek oral contraceptionPremenstrual dysphoric disorder in women who have chosen oral contraceptives as their method of birth control | To request a General Schedule unrestricted listing. |
| ELRANATAMAB Solution for subcutaneous injection 44 mg in 1.1 mL (40 mg per mL)Solution for subcutaneous injection 76 mg in 1.9 mL (40 mg per mL)Elrexfio®PFIZER AUSTRALIA PTY LTD(New PBS listing) | Relapsed or refractory multiple myeloma (RRMM) | To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for the treatment of RRMM in patients who have received at least three prior therapies. |
| ESKETAMINE Nasal spray solution 28 mg in 0.2 mL (2 actuations)Spravato®JANSSEN-CILAG PTY LTD(New PBS listing) | Treatment‑resistant depression | Resubmission to request a Section 100 (Highly Specialised Drug Program) Authority Required (Telephone/Online) listing for the treatment of treatment‑resistant depression. |
| ESTRADIOLTransdermal gel 500 micrograms (as hemihydrate) in 0.5 g sachetSandrena®ORION PHARMA (AUS) PTY LIMITED(New PBS listing) | Climacteric symptoms after natural or surgical menopause | To request a General Schedule unrestricted listing. |
| FARICIMAB Solution for intravitreal injection 28.8 mg in 0.24 mL (120 mg per mL)Vabysmo®ROCHE PRODUCTS PTY LTD(Change to existing listing) | Retinal vein occlusion (RVO) | To request a General Schedule Authority Required (Telephone/Online) listing for initial treatment and an Authority Required (STREAMLINED) listing for continuing treatment of RVO. |
| FRUQUINTINIB Capsule 1 mgCapsule 5 mgFruzaqla®TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD.(New PBS listing)TO BE CONSIDERED AT A FUTURE PBAC MEETING | Metastatic colorectal cancer (mCRC) | To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of patients with mCRC who have been previously treated with or who are not considered candidates for available therapies. |
| IPTACOPAN Capsule 200 mgFabhalta®NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED(New PBS listing) | Paroxysmal nocturnal hemoglobinuria (PNH) | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of adults with PNH who have inadequate clinical response to C5 inhibitor treatment.  |
| IVOSIDENIB Tablet 250 mgTibsovo®SERVIER LABORATORIES (AUST.) PTY. LTD.(New PBS listing) | Bile duct cancer (cholangiocarcinoma) | 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. |
| LANREOTIDEInjection 60 mg (as acetate) in single dose pre-filled syringeInjection 90 mg (as acetate) in single dose pre-filled syringeInjection 120 mg (as acetate) in single dose pre-filled syringeSomatuline® AutogelIPSEN PTY LTD(Change to existing listing) | AcromegalyFunctional Carcinoid TumourNon-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET) | To request an amendment to the clinical criteria of the Section 100 (Highly Specialised Drug Program) Authority Required (STREAMLINED) listings for the treatment of acromegaly, functional carcinoid tumour, and non-functional GEP-NET. |
| LECANEMAB Solution concentrate for I.V. infusion 200 mg in 2 mL (100 mg per mL)Solution concentrate for I.V. infusion 500 mg in 5 mL (100 mg per mL)Leqembi®EISAI AUSTRALIA PTY LTD(New PBS listing)TO BE CONSIDERED AT A FUTURE PBAC MEETING | Early Alzheimer disease (EAD) | To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of EAD, comprising mild cognitive impairment due to Alzheimer disease (AD), prodromal AD, or mild AD dementia. |
| LEVODOPA WITH CARBIDOPA AND ENTACAPONEIntestinal gel containing levodopa 20 mg with carbidopa monohydrate 5 mg and with entacapone 20 mg per mL, 47 mLLecigon®STADA PHARMACEUTICALS AUSTRALIA PTY LIMITED(New PBS listing) | Advanced Parkinson disease  | Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of advanced idiopathic Parkinson disease with severe motor fluctuations despite optimised alternative pharmacological treatment. |
| LINZAGOLIX Tablet 100 mg (as choline)Tablet 200 mg (as choline)Yselty®THERAMEX AUSTRALIA PTY LTD(New PBS listing) | Moderate to severe symptomatic uterine fibroids | To request General Schedule Authority Required (Telephone/Online) for initiation and Authority Required (STREAMLINED) continuing listings for the treatment of moderate to severe symptomatic uterine fibroids. |
| METHOTREXATETablet 2.5 mg (as sodium)Tablet 10 mg (as sodium)Methoblastin®PFIZER AUSTRALIA PTY LTD(New PBS listing) | Chemotherapy and inflammatory conditions | To request a General Schedule unrestricted listing of new forms and to request listing of a new pack size. |
| MILK POWDER -- SYNTHETICLow calcium oral powder 400 g (Locasol)Locasol®NUTRICIA AUSTRALIA PTY LIMITED(Change to existing listing) | Hypercalcaemia | To request Locasol with new formulation continue to be listed on the PBS under the existing conditions. |
| MORPHINETablet containing morphine sulfate pentahydrate 30 mgAnamorph®ARROW PHARMA PTY LTD(New PBS listing) | Severe pain, cancer pain, severe disabling pain | To request a General Schedule Restricted Benefit listing for the treatment of severe pain and cancer pain, and a Palliative Care Schedule Authority Required (Telephone/Online) listing for the treatment of severe disabling pain. |
| NIRSEVIMAB Solution for injection 50 mg in 0.5 mL pre‑filled syringeSolution for injection 100 mg in 1 mL pre‑filled syringeBeyfortus®SANOFI-AVENTIS AUSTRALIA PTY LTD(New PBS listing) | Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV) | To request a General Schedule Restricted Benefit listing for prevention of RSV lower respiratory tract disease in neonates and infants born during or entering their first RSV season; and children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. |
| NIVOLUMAB Injection concentrate for I.V. infusion 40 mg in 4 mLInjection concentrate for I.V. infusion 100 mg in 10 mLOpdivo®IPILIMUMABInjection concentrate for I.V. infusion 50 mg in 10 mLYervoy®BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD(Change to existing listing) | Unresectable malignant mesothelioma | To request the PBAC consider the previously estimated utilisation for nivolumab and ipilimumab for the treatment of unresectable malignant mesothelioma.  |
| ODEVIXIBAT Capsule 200 microgramsCapsule 400 microgramsCapsule 600 microgramsCapsule 1200 microgramsBylvay®IPSEN PTY LTD(New PBS listing) | Progressive familial intrahepatic cholestasis (PFIC) | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of PFIC. |
| OLAPARIB Tablet 100 mgTablet 150 mgLynparza®ASTRAZENECA PTY LTD(Change to existing listing) | Human epidermal growth factor 2 (HER2) negative metastatic breast cancer with a confirmed *BRCA1* or *BRCA2* mutation | To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of HER2-negative metastatic breast cancer for patients with a confirmed *BRCA1* or *BRCA2* mutation. |
| PRASUGRELTablet 5 mgTablet 10 mgPrasugrel SCPGENERIC HEALTH PTY LTD(New PBS listing) | Acute coronary syndrome  | Resubmission to request a General Schedule Authority Required (STREAMLINED) listing, in combination with aspirin, for the treatment of acute coronary syndrome (myocardial infarction or unstable angina) managed by percutaneous coronary intervention. |
| PROGESTERONECapsule 300 mgUtrogestan®BESINS HEALTHCARE AUSTRALIA PTY LTD(New PBS listing) | Luteal phase support | To request a Section 100 (In Vitro Fertilisation Program) Authority Required (STREAMLINED) listing of a new strength for luteal phase support as part of an assisted reproductive technology treatment cycle. |
| PROPYLENE GLYCOLEye drops 60 micrograms per mL, 10 mLSystane Balance®ALCON LABORATORIES (AUSTRALIA) PTY LTD(New PBS listing) | Severe dry eye syndrome | To request a General Schedule Restricted Benefit listing for the treatment of severe dry eye syndrome. |
| 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(New PBS listing) | Generalised myasthenia gravis (gMG) | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of adult patients with gMG who are anti-acetylcholine receptor antibody positive. |
| RESPIRATORY SYNCYTIAL VIRUS VACCINEPowder and suspension for injection (0.5 mL)Arexvy®GLAXOSMITHKLINE AUSTRALIA PTY LTD(New NIP listing) | Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV) | To request a National Immunisation Program listing for the prevention of RSV in patients aged 60 years and over.  |
| RISDIPLAM Powder for oral solution 750 micrograms per mL, 80 mLEvrysdi®ROCHE PRODUCTS PTY LTD(Change to existing listing) | Spinal muscular atrophy (SMA) | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of patients with confirmed genetic diagnosis of SMA (*SMA1* deletion or mutation) who have a *SMN2* gene copy number of 3. |
| SELPERCATINIB Capsule 40 mgCapsule 80 mgRetevmo®ELI LILLY AUSTRALIA PTY LTD(New PBS listing) | Non-small cell lung cancer (NSCLC) | Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of advanced or metastatic, rearranged during transfection (RET) fusion-positive NSCLC. |
| TALAZOPARIBCapsule 0.1 mg Capsule 0.25 mgCapsule 0.35 mgCapsule 0.5 mg Talzenna®PFIZER AUSTRALIA PTY LTD(New PBS listing) | Prostate cancer (PC) | Resubmission to request a General Schedule Authority Required (STREAMLINED) listing, in combination with enzalutamide, for the treatment of metastatic castration resistant PC in patients with a *BRCA1* or *BRCA2* mutation who have not received prior treatment with a novel hormonal agent. |
| VEDOLIZUMAB Powder for injection 300 mgEntyvio®TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD.(Change to existing listing) | Chronic pouchitis | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for initial treatment and an Authority Required (Telephone/Online) listing for continuing treatment of chronic pouchitis. |
| ZANUBRUTINIBCapsule 80 mgBrukinsa®BEIGENE AUS PTY LTD(Change to existing listing) | Waldenström macroglobulinaemia | To request the PBAC consider the previously estimated utilisation of zanubrutinib for the treatment of Waldenström macroglobulinaemia.  |
| ZILUCOPLAN Solution for injection 16.6 mg in 0.416 mL (as tetrasodium) pre-filled syringeSolution for injection 23 mg in 0.574 mL (as tetrasodium) pre-filled syringeSolution for injection 32.4 mg in 0.810 mL (as tetrasodium) pre-filled syringeZilbrysq®UCB AUSTRALIA PROPRIETARY LIMITED(New PBS listing) | Generalised myasthenia gravis (gMG) | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for initial treatment and a General Schedule Authority Required (Written) listing for continuing treatment of gMG. |
| BRENTUXIMAB VEDOTIN Powder for I.V. infusion 50 mg Adcetris®   TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD (Sub-committee reportDUSC Analysis) | Cutaneous and peripheral T-cell lymphoma | To review the written authority requirement for brentuximab vedotin for cutaneous and peripheral T-cell lymphoma. |
| GALCANEZUMABInjection 120 mg in 1 mL pre-filled penEmgality®ELI LILLY AUSTRALIA PTY LTDFREMANEZUMABSolution for injection 225 mg in 1.5 mL single dose pre-filled penSolution for injection 225 mg in 1.5 mL single dose pre-filled syringeAjovy®TEVA PHARMA AUSTRALIA PTY LTD(Sub-committee reportDUSC Analysis) | Chronic migraine | To assess the utilisation of PBS listed galcanezumab and fremanezumab for the treatment of chronic migraine. |
| SEMAGLUTIDE Solution for injection 2 mg in 1.5 mL pre-filled penSolution for injection 4 mg in 3 mL pre-filled pen Ozempic® Novo Nordisk Pharmaceuticals Pty. Limited   (Sub-committee reportDUSC Analysis) | Type 2 diabetes mellitus (T2DM) | To assess the utilisation of PBS listed semaglutide and other glucagon-like peptide 1 (GLP-1) analogues for the treatment of T2DM.    |
| AVELUMAB Solution concentrate for I.V. infusion 200 mg in 10 mLBavencio®MERCK HEALTHCARE PTY LTD(Review of positive PBAC recommendations not accepted by applicants) | Stage IV clear cell variant renal cell carcinoma | - |
| DULAGLUTIDEInjection 3 mg in 0.5 mL single dose pre-filled penInjection 4.5 mg in 0.5 mL single dose pre-filled penTrulicity®ELI LILLY AUSTRALIA PTY LTD(Review of positive PBAC recommendations not accepted by applicants) | Type 2 diabetes mellitus (T2DM) | - |
| HUMAN MENOPAUSAL GONADOTROPHINInjection 600 I.U. in 1.92 mL pre-filled multi-dose penInjection 1,200 I.U. in 1.92 mL pre-filled multi-dose penMenopur®FERRING PHARMACEUTICALS PTY LIMITED(Review of positive PBAC recommendations not accepted by applicants) | Assisted reproductive technology | - |
| IBRUTINIBCapsule 140 mgImbruvica®JANSSEN-CILAG PTY LTD(Review of positive PBAC recommendations not accepted by applicants) | Chronic lymphocytic leukaemia (CLL) and small lymphocytic lymphoma (SLL) with evidence of one or more 17p chromosome deletions | - |
| PANCREATIC EXTRACTCapsule (containing enteric coated minimicrospheres) providing not less than 20,000 BP units of lipase activityCreon®VIATRIS PTY LTD(Review of positive PBAC recommendations not accepted by applicants) | Cystic fibrosis | - |
| PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mLKeytruda®MERCK SHARP & DOHME (AUSTRALIA) PTY LIMITED(Review of positive PBAC recommendations not accepted by applicants) | Advanced or metastatic gastro-oesophageal cancers | - |
| PROGESTERONEPessary 400 mgCyclogest®GEDEON RICHTER AUSTRALIA PTY LTD(Review of positive PBAC recommendations not accepted by applicants) | Assisted reproductive technology | - |
| TRIENTINETablet 150 mg (as tetrahydrochloride)Cuprior®ORPHALAN(Review of positive PBAC recommendations not accepted by applicants) | Wilson disease | - |
| USTEKINUMAB Injection 90 mg in 1 mL pre-filled syringeStelara®JANSSEN-CILAG PTY LTD(Review of positive PBAC recommendations not accepted by applicants) | Crohn diseaseSevere chronic plaque psoriasis | - |
| OCULAR LUBRICANTS FOR THE TREATMENT OF SEVERE DRY EYE SYNDROMEAll brands and strengths Various sponsorsDEPARTMENT OF HEALTH AND AGED CARE (Other matters) | Severe dry eye syndrome | To provide the PBAC with the findings following a systematic literature review comparing the efficacy and safety of preservative-containing ocular lubricants versus preservative-free ocular lubricants in patients with severe dry eye syndrome. |
| OSTEOPOROSIS THERAPY RESTRICTIONS REVIEWALENDRONATERISEDRONATEZOLEDRONIC ACIDVarious forms and strengthsVarious brandsVarious sponsors(Change to existing listing) | Osteoporosis | To consider the impact of potential broadening of restrictions for osteoporosis therapies. This matter was deferred at the September 2021PBAC meeting. |
| SODIUM-GLUCOSE COTRANSPORTER 2 (SGLT2) INHIBITORS FOR THE TREATMENT OF TYPE 2 DIABETES MELLITUS DAPAGLIFLOZINSAXAGLIPTIN WITH DAPAGLIFLOZINDAPAGLIFLOZIN WITH METFORMINAll forms and strengthsForxiga®Qtern® 5/10Xigduo® XRASTRAZENECA PTY LTDEMPAGLIFLOZINEMPAGLIFOZIN WITH LINAGLIPTINEMPAGLIFLOZIN WITH METFORMINAll forms and strengthsJardiance®Glyxambi®Jardiamet®BOEHRINGER INGELHEIM PTY LTD(Change to existing listing) | Type 2 diabetes mellitus (T2DM) | To request the PBAC reconsider its March 2022 recommendation and the estimated costs for SGLT2 inhibitors (dapagliflozin and empagliflozin) to be listed as add-on therapy to metformin for the treatment of T2DM patients with cardiovascular disease or high cardiovascular risk |
| REVIEW OF ITEMS FOR NURSE PRACTITIONER AND ENDORSED MIDWIFE PRESCRIBING ON THE PHARMACEUTICAL BENEFITS SCHEMEVarious forms and strengthsVarious brandsVarious sponsors(Other matters) | Various medicines | To seek the PBAC’s consideration of a list of medicines with a Shared Care Model (SCM) administrative note for nurse practitioner prescribing, and advice on whether the SCM note continues to be appropriate for specific listings. |

Version 6

Items added or amended

* + - * 1. ARIPIPRAZOLE (Abilify Asimtufii®) – To be considered at a future PBAC meeting
				2. FRUQUINTINIB (Fruzaqla®) – To be considered at a future PBAC meeting

Items added or amended previously

* + - * 1. LECANEMAB (Leqembi®) - To be considered at a future PBAC meeting
				2. MORPHINE (Anamorph®) – Added
				3. RAVULIZUMAB (Ultomiris®) - Added
				4. AVELUMAB (Bavencio®) – Sponsor amended
				5. REVIEW OF ITEMS FOR NURSE PRACTITIONER AND ENDORSED MIDWIFE PRESCRIBING ON THE PHARMACEUTICAL BENEFITS SCHEME (Various brands) – Added
				6. ADRENALINE (EPINEPHRINE) (Jext® Jnr; Jext®) – Sponsor amended
				7. LEVODOPA WITH CARBIDOPA AND ENTACAPONE (Lecigon®) – Added
				8. ODEVIXIBAT (Bylvay®) – Purpose of submission amended
				9. PRASUGREL (Prasugrel SCP) – Added
				10. TALAZOPARIB (Talzenna®) – Added
				11. AVELUMAB (Bavencio®) – Review of positive PBAC recommendations not accepted by applicants – Added
				12. DULAGLUTIDE (Trulicity®) - Review of positive PBAC recommendations not accepted by applicants – Added
				13. HUMAN MENOPAUSAL GONADOTROPHIN (Menopur®) - Review of positive PBAC recommendations not accepted by applicants – Added
				14. IBRUTINIB (Imbruvica®) - Review of positive PBAC recommendations not accepted by applicants – Added
				15. PANCREATIC EXTRACT (Creon®) – Review of positive PBAC recommendations not accepted by applicants – Added
				16. PEMBROLIZUMAB (Keytruda®) – Review of positive PBAC recommendations not accepted by applicants – Added
				17. PROGESTERONE (Cyclogest®) – Review of positive PBAC recommendations not accepted by applicants – Added
				18. TRIENTINE (Cuprior®) - Review of positive PBAC recommendations not accepted by applicants – Added
				19. USTEKINUMAB (Stelara®) - Review of positive PBAC recommendations not accepted by applicants – Added
				20. OCULAR LUBRICANTS FOR THE TREATMENT OF SEVERE DRY EYE SYNDROME (Various brands) – Added
				21. OSTEOPOROSIS THERAPY RESTRICTIONS REVIEW (Various brands) – Added
				22. SODIUM-GLUCOSE COTRANSPORTER 2 (SGLT2) INHIBITORS FOR THE TREATMENT OF TYPE 2 DIABETES MELLITUS (Various brands) – Added
				23. FARICIMAB (Vabysmo®) – Form, submission type and purpose of submission amended
				24. FRUQUINTINIB (Fruzaqla®) – Form amended