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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.) |
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| ADALIMUMAB  Injection 20 mg in 0.2 mL pre-filled syringe Injection 40 mg in 0.4 mL pre-filled syringe Injection 40 mg in 0.4 mL pre-filled pen Injection 80 mg 0.8 mL pre-filled syringe Injection 80 mg in 0.8 mL pre-filled pen  Hyrimoz®  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 injector I.M. injection 300 micrograms in 0.3 mL (as acid tartrate) single dose syringe auto injector  Jext® Jnr Jext®  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. |
| APALUTAMIDE  Tablet 240 mg  Erlyand®  JANSSEN-CILAG PTY LTD  (New PBS listing) | Non-metastatic castration-resistant carcinoma of the prostate Metastatic 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. |
| ARIPIPRAZOLE  I.M. injection (modified release) 720 mg in 2.4 mL pre-filled syringe I.M. injection (modified release) 960 mg in 3.2 mL pre-filled syringe  Abilify 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. |
| BELZUTIFAN  Tablet 40 mg  Welireg®  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. |
| BLINATUMOMAB  Powder for I.V. infusion 38.5 micrograms  Blincyto®  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 mg  Visanne®  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 tablets  Yaz®  Pack containing 21 tablets 3 mg drospirenone with 30 micrograms ethinylestradiol and 7 inert tablets  Yasmin®  BAYER AUSTRALIA LTD  (New PBS listing) | Oral contraceptive Moderate acne vulgaris in women who seek oral contraception Premenstrual 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. |
| ESTRADIOL  Transdermal gel 500 micrograms (as hemihydrate) in 0.5 g sachet  Sandrena®  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 mg  Capsule 5 mg  Fruzaqla®  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 mg  Fabhalta®  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 mg  Tibsovo®  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. |
| LANREOTIDE  Injection 60 mg (as acetate) in single dose pre-filled syringe Injection 90 mg (as acetate) in single dose pre-filled syringe Injection 120 mg (as acetate) in single dose pre-filled syringe  Somatuline® Autogel  IPSEN PTY LTD  (Change to existing listing) | Acromegaly Functional Carcinoid Tumour Non-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)  WITHDRAWN | 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 ENTACAPONE  Intestinal gel containing levodopa 20 mg with carbidopa monohydrate 5 mg and with entacapone 20 mg per mL, 47 mL  Lecigon®  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. |
| METHOTREXATE  Tablet 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 -- SYNTHETIC  Low 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. |
| MORPHINE  Tablet containing morphine sulfate pentahydrate 30 mg  Anamorph®  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 syringe Solution for injection 100 mg in 1 mL pre‑filled syringe  Beyfortus®  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 mL  Injection concentrate for I.V. infusion 100 mg in 10 mL  Opdivo®  IPILIMUMAB  Injection concentrate for I.V. infusion 50 mg in 10 mL  Yervoy®  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 micrograms Capsule 400 micrograms Capsule 600 micrograms Capsule 1200 micrograms  Bylvay®  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 mg Tablet 150 mg  Lynparza®  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. |
| PRASUGREL  Tablet 5 mg Tablet 10 mg  Prasugrel SCP  GENERIC 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. |
| PROGESTERONE  Capsule 300 mg  Utrogestan®  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 GLYCOL  Eye drops 60 micrograms per mL, 10 mL  Systane 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. |
| RAVULIZUMAB  Solution concentrate for I.V. infusion 300 mg in 3 mL  Solution concentrate for I.V. infusion  1,100 mg in 11 mL  Ultomiris®  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 VACCINE  Powder 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 mL  Evrysdi®  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 mg Capsule 80 mg  Retevmo®  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. |
| TALAZOPARIB  Capsule 0.1 mg  Capsule 0.25 mg  Capsule 0.35 mg  Capsule 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 mg  Entyvio®  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. |
| ZANUBRUTINIB  Capsule 80 mg  Brukinsa®  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 syringe Solution for injection 23 mg in 0.574 mL (as tetrasodium) pre-filled syringe Solution for injection 32.4 mg in 0.810 mL (as tetrasodium) pre-filled syringe  Zilbrysq®  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 report  DUSC Analysis) | Cutaneous and peripheral T-cell lymphoma | To review the written authority requirement for brentuximab vedotin for cutaneous and peripheral T-cell lymphoma. |
| GALCANEZUMAB  Injection 120 mg in 1 mL pre-filled pen  Emgality®  ELI LILLY AUSTRALIA PTY LTD  FREMANEZUMAB  Solution for injection 225 mg in 1.5 mL single dose pre-filled pen  Solution for injection 225 mg in 1.5 mL single dose pre-filled syringe  Ajovy®  TEVA PHARMA AUSTRALIA PTY LTD  (Sub-committee report  DUSC 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 pen  Solution for injection 4 mg in 3 mL pre-filled pen    Ozempic®  Novo Nordisk Pharmaceuticals Pty. Limited    (Sub-committee report  DUSC 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 mL  Bavencio®  MERCK HEALTHCARE PTY LTD  (Review of positive PBAC recommendations not accepted by applicants) | Stage IV clear cell variant renal cell carcinoma | - |
| DULAGLUTIDE  Injection 3 mg in 0.5 mL single dose pre-filled pen  Injection 4.5 mg in 0.5 mL single dose pre-filled pen  Trulicity®  ELI LILLY AUSTRALIA PTY LTD  (Review of positive PBAC recommendations not accepted by applicants) | Type 2 diabetes mellitus (T2DM) | - |
| HUMAN MENOPAUSAL GONADOTROPHIN  Injection 600 I.U. in 1.92 mL pre-filled multi-dose pen  Injection 1,200 I.U. in 1.92 mL pre-filled multi-dose pen  Menopur®  FERRING PHARMACEUTICALS PTY LIMITED  (Review of positive PBAC recommendations not accepted by applicants) | Assisted reproductive technology | - |
| IBRUTINIB  Capsule 140 mg  Imbruvica®  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 EXTRACT  Capsule (containing enteric coated minimicrospheres) providing not less than 20,000 BP units of lipase activity  Creon®  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 mL  Keytruda®  MERCK SHARP & DOHME (AUSTRALIA) PTY LIMITED  (Review of positive PBAC recommendations not accepted by applicants) | Advanced or metastatic gastro-oesophageal cancers | - |
| PROGESTERONE  Pessary 400 mg  Cyclogest®  GEDEON RICHTER AUSTRALIA PTY LTD  (Review of positive PBAC recommendations not accepted by applicants) | Assisted reproductive technology | - |
| TRIENTINE  Tablet 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 syringe  Stelara®  JANSSEN-CILAG PTY LTD  (Review of positive PBAC recommendations not accepted by applicants) | Crohn disease  Severe chronic plaque psoriasis | - |
| OCULAR LUBRICANTS FOR THE TREATMENT OF SEVERE DRY EYE SYNDROME  All brands and strengths   Various sponsors  DEPARTMENT 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 REVIEW  ALENDRONATE  RISEDRONATE  ZOLEDRONIC ACID  Various forms and strengths  Various brands  Various 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 2021  PBAC meeting. |
| SODIUM-GLUCOSE COTRANSPORTER 2 (SGLT2) INHIBITORS FOR THE TREATMENT OF TYPE 2 DIABETES MELLITUS   DAPAGLIFLOZIN  SAXAGLIPTIN WITH DAPAGLIFLOZIN  DAPAGLIFLOZIN WITH METFORMIN  All forms and strengths  Forxiga®  Qtern® 5/10  Xigduo® XR  ASTRAZENECA PTY LTD  EMPAGLIFLOZIN  EMPAGLIFOZIN WITH LINAGLIPTIN  EMPAGLIFLOZIN WITH METFORMIN  All forms and strengths  Jardiance®  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 SCHEME  Various forms and strengths  Various brands  Various 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 7

Items added or amended

* + - * 1. LECANEMAB (Leqembi®) – Withdrawn

Items added or amended previously

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