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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, PBS schedule** (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, requested authority level** (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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| 21-VALENT PNEUMOCOCCAL CONJUGATE VACCINE  Injection, 0.5 mL  Capvaxive®  MERCK SHARP & DOHME (AUSTRALIA) PTY LTD  (New NIP listing) | Prevention of pneumococcal disease in adults | To request a National Immunisation Program (NIP) listing for the prevention of pneumococcal disease for:   * adults who are currently eligible to receive the 13-valent pneumococcal conjugate vaccine under the NIP (adults under 70 with specified medical risk conditions, Aboriginal and Torres Strait Islander adults over 50 years of age, and all adults over 70 years of age) and * Aboriginal and Torres Strait Islander people aged 25 to 49. |
| ACALABRUTINIB  Tablet 100 mg  Calquence®  ASTRAZENECA PTY LTD  (Change to existing listing)  PBS General Schedule | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) | To request listing of acalabrutinb for use in combination with venetoclax for the treatment of previously untreated CLL or SLL.  Authority Required (Telephone/Online) |
| AFLIBERCEPT  Solution for intravitreal injection 2 mg in 50 microlitres (40 mg per mL) Solution for intravitreal injection 2 mg in 50 microlitres (40 mg per mL) pre‑filled syringe  Eydenzelt®  CELLTRION HEALTHCARE AUSTRALIA PTY LTD  (New PBS listing)  PBS General Schedule | Subfoveal choroidal neovascularisation (CNV) due to pathologic myopia (PM) | To request listing of a new aflibercept biosimilar for the treatment of CNV due to PM that mirrors the originator brand’s current listing.  Authority Required |
| BELANTAMAB MAFODOTIN  Powder for injection 70 mg (50 mg per ml) Powder for injection 100 mg (50 mg per ml)  Blenrep®  GLAXOSMITHKLINE AUSTRALIA PTY LTD  (New PBS listing)  PBS S100 Efficient Funding of Chemotherapy Program | Relapsed and/or refractory multiple myeloma (MM) | To request listings of belantamab mafodotin for use in combination with bortezomib and dexamethasone for initial and continuing treatment of relapsed and/or refractory MM after one prior line of therapy.  Authority Required (Telephone/Online) listing for initial treatment  Authority Required (STREAMLINED) listing for continuing treatment |
| BIMEKIZUMAB  Injection 320 mg in 2 mL single use pre-filled pen  Bimzelx®  UCB AUSTRALIA PROPRIETARY LIMITED  (New PBS listing)  PBS General Schedule | Severe chronic plaque psoriasis (CPP) | To request a listing of a new strength of bimekizumab for the treatment of severe CPP.  Authority Required |
| CALCIPOTRIOL WITH BETAMETHASONE  Gel containing calcipotriol 50 micrograms with betamethasone 500 micrograms (as dipropionate) per g, 60 g  Actobet®  ACTOR PHARMACEUTICALS PTY LTD  (New PBS listing)  PBS General Schedule | Chronic stable plaque type psoriasis vulgaris | To request listing of a new form of calcipotriol with betamethasone for the treatment of chronic stable plaque type psoriasis vulgaris.  Restricted Benefit |
| CETRORELIX  Solution for injection 250 micrograms (as acetate) in 1 mL single use pre‑filled syringe  Femvi®  SUN PHARMA ANZ PTY LTD  (New PBS listing)  PBS Section 100 (In Vitro Fertilisation Program) | Assisted Reproductive Technology (ART) | To request a listing of a new form of cetrorelix for use in ART.  Authority Required (STREAMLINED) |
| DELGOCITINIB  Cream 20 mg per g, 60 g  Anzupgo®  LEO PHARMA PTY LTD  (New PBS listing)  PBS General Schedule | Chronic hand eczema (CHE) | To request listing of delgocitinib for the treatment of moderate to severe CHE where topical corticosteroids failed to achieve an adequate response or are medically inappropriate.  Authority Required (Written) |
| DENOSUMAB  Injection 60 mg in 1 mL pre-filled syringe  Stoboclo®  Injection 120 mg in 1.7 mL  Osenvelt®  CELLTRION HEALTHCARE AUSTRALIA PTY LTD  (New PBS listing)  PBS General Schedule | Osteoporosis Giant cell tumour of bone Bone metastases | To request listings of two new denosumab biosimilars that mirror their respective originator brand’s current listings.  Authority Required (STREAMLINED) |
| DURVALUMAB  Solution concentrate for I.V infusion, 120 mg in 2.4 mL Solution concentrate for I.V. infusion, 500 mg in 10 mL  Imfinzi®  ASTRAZENECA PTY LTD  (Change to existing listing)  PBS Section 100 (Efficient Funding of Chemotherapy Program) | Muscle invasive bladder cancer (MIBC) | To request listing of durvalumab for the perioperative treatment (i.e. before and after surgery) of patients with MIBC who are planning to undergo radical cystectomy and are eligible for cisplatin-based neoadjuvant chemotherapy (i.e. eligible for cisplatin-based chemotherapy given prior to surgery).  Authority Required (STREAMLINED) |
| EFGARTIGIMOD ALFA  Solution for subcutaneous injection 1000 mg in 5.6 mL  Vyvgart®  ARGENX AUSTRALIA PTY. LTD.  (New PBS listing)  PBS General Schedule | Generalised myasthenia gravis (gMG) | To request a subcutaneous injection form of efgartigimod alfa for initial and continuing treatment of adult patients with gMG who are anti-acetylcholine receptor antibody positive.  Authority Required |
| ENCORAFENIB  Capsule 75 mg  Braftovi®  BINIMETINIB  Tablet 15 mg Tablet 45 mg  Mektovi®  PIERRE FABRE AUSTRALIA PTY LTD  (New PBS listing)  PBS General Schedule | Non-small cell lung cancer (NSCLC) | To request listing of encorafenib for use in combination with binimetinib for the treatment of adult patients with advanced or metastatic NSCLC with a BRAF V600E mutation who have not received prior systemic treatment in the metastatic setting.  Authority Required (STREAMLINED) |
| ESTRADIOL WITH PROGESTERONE  Capsule containing estradiol 1mg (as hemihydrate) with progesterone 100mg  Bijuva®  THERAMEX AUSTRALIA PTY LTD  (New PBS listing)  PBS General Schedule | Vasomotor symptoms in post-menopausal women | To request listing of estradiol with progesterone for the treatment of moderate to severe vasomotor symptoms in post-menopausal women.  Restricted Benefit |
| FEDRATINIB  Capsule 100 mg  Inrebic®  BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD  (New PBS listing)  PBS General Schedule | Myelofibrosis (MF) | Resubmission to request listing of fedratinib for the treatment of patients with intermediate/high-risk primary myelofibrosis, post-polycythaemia vera myelofibrosis, or post-essential thrombocythaemia myelofibrosis.  Authority Required (Telephone/Online) |
| FENFLURAMINE  Oral solution 2.2 mg (as hydrochloride) per mL, 360 mL  Fintepla®  UCB AUSTRALIA PROPRIETARY LIMITED  (Change to existing listing)  PBS General Schedule | Lennox-Gastaut Syndrome (LGS) | To request listing of fenfluramine as add-on therapy for patients with LGS who are not adequately controlled with at least two other anti-epileptic drugs.  Authority Required (Telephone/Online) |
| FEZOLINETANT  Tablet 45 mg  Veoza®  ASTELLAS PHARMA AUSTRALIA PTY LTD  (New PBS listing)  PBS General Schedule | Moderate to severe menopause-related vasomotor symptoms (VMS) | Resubmission to request listing of fezolinetant for the treatment of moderate to severe menopause-related VMS for whom menopausal hormone therapy is not suitable.  Authority Required (STREAMLINED) |
| FUTIBATINIB  Tablet 4 mg  Lytgobi® TAIHO PHARMA OCEANIA PTY LTD  (New PBS listing) PBS General Schedule | Bile duct cancer  (cholangiocarcinoma) | Resubmission to request listing of futibatinib for the treatment of patients with locally advanced or metastatic cholangiocarcinoma who have previously progressed on systemic therapy and have a fibroblast growth factor receptor 2 fusion or rearrangement.   Authority Required (STREAMLINED) |
| GLYCOPYRRONIUM  Cream containing glycopyrronium (as bromide) 8 mg per g (2.2 mg per actuation), 50 g  Axhidrox®  ACTOR PHARMACEUTICALS PTY LTD  (New PBS listing)  PBS General Schedule | Primary axillary hyperhidrosis | To request listing of glycopyrronium for the treatment of patients aged 18 years and older with severe primary axillary hyperhidrosis.  Authority Required (STREAMLINED) |
| IPTACOPAN  Capsule 200 mg  Fabhalta®  NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED  (Change to existing listing)  PBS General Schedule | Complement 3 glomerulopathy (C3G) | To request listing of iptacopan for the treatment of adults with C3G with either native kidneys or disease recurrence following a kidney transplant.  Authority Required (Written) |
| Life Saving Drugs Program (LSDP) medicines for Gaucher disease (type 1)  ELIGLUSTAT  Capsule containing eliglustat tartrate, 100 mg  Cerdelga®  IMIGLUCERASE  Powder for IV infusion, 400 units  Cerezyme®  TALIGLUCERASE ALFA  Powder for IV infusion, 200 units  Elelyso®  VELAGLUCERASE ALFA  Powder for IV infusion, 400 units  Vpriv®  Various sponsors  (New PBS listing) | Gaucher disease (type 1) (GD1) | Referral from the LSDP Expert Panel seeking the PBAC’s advice on whether eliglustat, imiglucerase, taliglucerase alfa, velaglucerase afla, would be cost-effective and suitable for PBS listing for the treatment of GD1. This matter was deferred at the July 2025 PBAC Meeting. |
| Life Saving Drugs Program (LSDP)  medicine for hereditary tyrosinaemia type 1  NITISINONE  Capsule 2 mg Capsule 5 mg Capsule 10 mg Capsule 20 mg Oral suspension 4 mg per mL, 90 mL  Orfadin®  A.MENARINI AUSTRALIA PTY LIMITED  (New PBS listing) | Hereditary tyrosinaemia type 1  (HT-1) | Referral from the LSDP Expert Panel seeking the PBAC’s advice on whether nitisinone would be cost-effective and suitable for PBS listing for the treatment of HT-1. This matter was deferred at the July 2025 PBAC Meeting. |
| LURBINECTEDIN  Powder for I.V. infusion 2 mg Powder for I.V. infusion 4 mg  Zepzelca®  SPECIALISED THERAPEUTICS PHARMA PTY LTD  (New PBS listing)  PBS Section 100 (Efficient Funding of Chemotherapy Program) | Small cell lung cancer (SCLC) | To request listing of lurbinectedin for use in combination with atezolizumab for first line maintenance treatment of extensive-stage SCLC for patients who have not progressed on or after first line induction therapy with atezolizumab, a platinum-based antineoplastic drug, and etoposide.  Authority Required (STREAMLINED) |
| OMAVELOXOLONE  Capsule 50 mg  Skyclarys®  BIOGEN AUSTRALIA PTY LTD  (New PBS listing)  PBS General Schedule | Friedreich’s ataxia | Resubmission to request listing of omaveloxolone for the treatment of Friedreich’s ataxia in people aged 16 years and older.  Authority Required (Telephone/Online) |
| ONASEMNOGENE ABEPARVOVEC  Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL Pack containing 3 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL Pack containing 4 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL Pack containing 5 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL Pack containing 6 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL Pack containing 7 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL Pack containing 8 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL Pack containing 9 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL  Zolgensma®  NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED  (Change to existing listing)  PBS Section 100 (Highly Specialised Drugs Program) | Spinal muscular atrophy (SMA) | To expand the current PBS listing for onasemnogene abeparvovec for the treatment of SMA to include paediatric patients weighing up to 21 kg.  Authority Required (Written) |
| OSIMERTINIB  Tablet 40 mg Tablet 80 mg  Tagrisso®  ASTRAZENECA PTY LTD  (Change to existing listing)  PBS General Schedule  To be considered at the September 2025 PBAC meeting\* | Non-small cell lung cancer  (NSCLC) | Resubmission to request listing of osimertinib for first line treatment of Stage IIIB (locally advanced) or Stage IV (metastatic) epidermal growth factor receptor mutation-positive (EGFRm) NSCLC in combination with pemetrexed and platinum-based chemotherapy.  Authority Required (Telephone/Online) |

\* Please note that consumer comments for OSIMERTINIB (Tagrisso®) will close on 19 August 2025.

| **Drug Name, form(s), strength(s) and Sponsor, Submission type, PBS schedule** (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, requested authority level** (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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| PEGCETACOPLAN  Solution for intravitreal injection 15 mg in 0.1 mL (150 mg per mL)  Syfovre®  APELLIS AUSTRALIA PTY LTD  (New PBS listing)  PBS General Schedule | Bilateral geographic atrophy (GA) secondary to age-related macular degeneration (AMD) | To request listing of pegcetacoplan for initial and continuing treatment of bilateral GA secondary to AMD where the treated eye has an intact fovea and central vision is threatened by growth of GA lesions and the non-treated eye does not have an intact fovea.  Authority Required (Written or Telephone/Online) initial treatment  Authority Required (STREAMLINED) for continuing treatment |
| PEMBROLIZUMAB  Solution concentrate for I.V. infusion 100 mg in 4 mL  Keytruda®  MERCK SHARP & DOHME (AUSTRALIA) PTY LTD  (Change to existing listing)  PBS Section 100 (Efficient Funding of Chemotherapy Program) | Head and neck squamous cell carcinoma (HNSCC) | To request listing of pembrolizumab for the neoadjuvant treatment (i.e. prior to the main treatment) of patients with resectable locally advanced HNSCC, continued as adjuvant treatment (i.e. after the main treatment) in combination with radiotherapy with or without chemotherapy, and then as a single agent.  Authority Required (STREAMLINED) |
| POLYETHYLENE GLYCOL 400 WITH PROPYLENE  GLYCOL  Eye drops 4 mg-3 mg per mL, single dose units 0.8 mL, 28  Systane®  ALCON LABORATORIES (AUSTRALIA) PTY LTD  (New PBS listing)  PBS General Schedule | Severe dry eye syndrome | To request listing of a new pack size of Systane (i.e. from 30 x 0.8 mL unit doses to 28 x 0.8 mL unit doses) for the treatment of severe dry eye syndrome.  Authority Required (STREAMLINED) |
| RECOMBINANT ZOSTER VACCINE  Powder and suspension for injection (0.5mL)  Shingrix®  GLAXOSMITHKLINE AUSTRALIA PTY LTD  (Change to existing NIP listing) | Prevention of herpes zoster virus | To request a National Immunisation Program listing with age eligibility criteria for non-Indigenous adults reduced from individuals aged 65 years of age and over to individuals aged 60 years of age and over. |
| RESPIRATORY SYNCYTIAL VIRUS VACCINE  Solution for injection 50 µg in 0.5 mL pre-filled syringe  mResvia®  MODERNA 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 lower respiratory tract disease caused by RSV in individuals aged over 75 years and Aboriginal and Torres Strait Islander people aged over 60 years. |
| RETIFANLIMAB  Solution concentrate for I.V. infusion 500 mg in 20 mL  Zynyz®  SPECIALISED THERAPEUTICS ALIM PTY LTD  (New PBS listing)  PBS Section 100 (Efficient Funding of Chemotherapy Program) | Merkel cell carcinoma (MCC) | To request listing of retifanlimab for the treatment of metastatic or recurrent, locally advanced MCC not amenable to curative surgery or radiation.  Authority Required (STREAMLINED) |
| RETIFANLIMAB  Solution concentrate for I.V. infusion 500 mg in 20 mL  Zynyz®  SPECIALISED THERAPEUTICS ALIM PTY LTD  (New PBS listing)  PBS Section 100 (Efficient Funding of Chemotherapy Program) | Squamous cell anal carcinoma (SCAC) | To request listing of retifanlimab for use in combination with carboplatin and paclitaxel for the treatment of inoperable locally recurrent or metastatic SCAC not previously treated with systemic chemotherapy.  Authority Required (STREAMLINED) |
| RISDIPLAM  Tablet 5 mg  Evrysdi®  ROCHE PRODUCTS PTY LTD  (New PBS listing)  PBS General Schedule | Spinal muscular atrophy (SMA) | To request listing of a new form of risdiplam for the treatment of SMA.  Authority Required |
| SEMAGLUTIDE  Solution for injection 0.25 mg in 0.5 mL single dose pre-filled pen  Solution for injection 0.5 mg in 0.5 mL single dose pre-filled pen  Solution for injection 1 mg in 0.5 mL single dose pre-filled pen  Solution for injection 1.7 mg in 0.75 mL single dose pre-filled pen  Solution for injection 2.4mg in 0.75mL single dose pre-filled pen  Wegovy®  NOVO NORDISK PHARMACEUTICALS PTY. LIMITED  (New PBS listing)  PBS General Schedule | Established cardiovascular disease (eCVD) with obesity | Resubmission to request listing of semaglutide for the treatment of patients with eCVD living with overweight or obesity.  Authority Required (Telephone/Online) |
| SPESOLIMAB  Solution for injection 300 mg in 2 mL single use pre-filled syringe  Spevigo®  BOEHRINGER INGELHEIM PTY LTD  (New PBS listing)  PBS Section 100 (Highly Specialised Drugs Program) | Prevention of generalised pustular psoriasis flares | To request listing of spesolimab for the prevention of generalised pustular psoriasis flares in patients aged ³ 12 years who have a high risk of generalised pustular psoriasis flares due to their background flare history.  Authority Required (Telephone/Online) |
| TAFASITAMAB  Powder for I.V. infusion 200 mg  Minjuvi®  SPECIALISED THERAPEUTICS ALIM PTY LTD  (New PBS listing)  PBS Section 100 (Efficient Funding of Chemotherapy Program) | Relapsed and/or refractory follicular lymphoma (FL) | To request listing of tafasitamab for use in combination with lenalidomide and rituximab for the treatment of patients with relapsed and/or refractory FL.  Authority Required (Telephone/Online) |
| TESTOSTERONE  Transdermal cream 10 mg per mL, 50 mL  AndroFeme 1®  LAWLEY PHARMACEUTICALS PTY LTD  (New PBS listing)  PBS General Schedule | Hypoactive sexual desire dysfunction (HSDD) | To request listing of testosterone for the treatment of HSDD in postmenopausal women that have failed to be treated by appropriate education and correction of modifiable biopsychosocial factors according to the International Society for the Study of Women’s Sexual Health process of care.  Restricted Benefit |
| TEZEPELUMAB  Solution for injection 210 mg in 1.91 mL single dose pre-filled pen (110 mg per mL)  Tezspire®  ASTRAZENECA PTY LTD  (New PBS listing)  PBS Section 100 (Highly Specialised Drugs Program) | Asthma | To request listing for the treatment of severe uncontrolled asthma in patients 12 years and older who have failed to achieve adequate control with optimised asthma therapy.  Authority Required (Written) |
| TOCILIZUMAB  Concentrate for injection 80 mg in 4 mL Concentrate for injection 200 mg in 10 mL Concentrate for injection 400 mg in 20 mL Injection 162 mg in 0.9 mL single use pre-filled pen Injection 162 mg in 0.9 mL single use pre-filled syringe  Avtozma®  CELLTRION HEALTHCARE AUSTRALIA PTY LTD  (New PBS listing)  PBS General Schedule  PBS Section 100 (Highly Specialised Drugs Program) | Severe active juvenile idiopathic arthritis Severe active rheumatoid arthritis Systemic juvenile idiopathic arthritis Active giant cell arteritis | To request listings of a new tocilizumab biosimilar that mirrors the originator brand’s current listings.  Authority Required |
| TOFERSEN  Solution for intrathecal injection 100 mg in 15 mL   Qalsody®  BIOGEN AUSTRALIA PTY LTD  (New PBS listing)  PBS Section 100 (Highly Specialised Drugs Program) | Amyotrophic lateral sclerosis (ALS) | To request listing of tofersen for the treatment of ALS associated with a mutation in the superoxide dismutase 1 gene in patients who have not experienced respiratory failure.  Authority Required (Telephone/Online) |
| TUCATINIB  Tablet 50 mg Tablet 150mg  Tukysa®  PFIZER AUSTRALIA PTY LTD  (New PBS listing)  General Schedule | Breast cancer | Resubmission to request a listing of tucatinib for use in combination with trastuzumab and capecitabine for the treatment of metastatic (Stage IV) human epidermal growth factor receptor 2 positive breast cancer in patients who have received two prior lines of HER2-directed therapy and have progressed on trastuzumab deruxtecan.  Authority Required (STREAMLINED) |
| VEDOLIZUMAB  Powder for injection 300 mg  Entyvio®  TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD.  (Change to existing listing)  PBS Section 100 (Highly Specialised Drugs Program) | Severe Crohn disease (CD) Moderate to severe ulcerative colitis (MSUC) | To request a change to the existing listings for vedolizumab (powder for injection 300 mg) for severe CD and MSUC, that is, additional restrictions with increased repeats to allow for dosing every 4 weeks.  Authority Required |
| WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, AND LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE  Oral powder 400 g, 6 (Renastart)  Renastart®  VITAFLO AUSTRALIA PTY LIMITED  (Change to existing listing)  TO BE CONSIDERED AT A FUTURE PBAC MEETING | Chronic Renal Failure | To request a minor formulation change to Renastart for the treatment of chronic renal failure. |
| ZANUBRUTINIB  Tablet 160 mg  Brukinsa®  BEIGENE AUS PTY LTD  (New PBS listing)  PBS General Schedule | Mantle cell lymphoma (MCL) Waldenstrom macroglobulinaemia (WM) Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) | To request listing of a new form of zanubrutinib for the treatment of MCL, WM, and CLL or SLL.  Authority Required |
| Medicines for chronic lymphocytic leukaemia or small lymphocytic lymphoma   All brands and strengths   Various sponsors   (DUSC analysis) | Chronic lymphocytic leukaemia or small lymphocytic lymphoma | To assess the utilisation of PBS listed medicines for the treatment of chronic lymphocytic leukaemia or small lymphocytic lymphoma. |
| DARATUMUMAB   Solution for subcutaneous injection 1,800 mg in 15 mL vial   Darzalex SC®   JANSSEN-CILAG PTY LTD   (DUSC analysis) | Amyloid light-chain (AL) amyloidosis | To assess the utilisation of daratumumab in combination with cyclophosphamide, bortezomib and dexamethasone for the treatment of patients with newly diagnosed AL amyloidosis. |
| ELEXACAFTOR, TEZACAFTOR AND IVACAFTOR   Pack containing 56 tablets of elexacaftor 100 mg with tezacaftor 50 mg and ivacaftor 75 mg and 28 tablets of ivacaftor 150 mg  Pack containing 56 tablets of elexacaftor 50 mg with tezacaftor 25 mg and ivacaftor 37.5 mg and 28 tablets of ivacaftor 75 mg  Pack containing 28 sachets elexacaftor 100 mg with tezacaftor 50 mg and with ivacaftor 75 mg and 28 sachets ivacaftor 75 mg  Pack containing 28 sachets elexacaftor 80 mg with tezacaftor 40 mg and with ivacaftor 60 mg and 28 sachets ivacaftor 59.5 mg  Trikafta®   VERTEX PHARMACEUTICALS (AUSTRALIA) PTY. LTD.   (DUSC analysis) | Cystic fibrosis | To assess the utilisation of PBS listed elexacaftor with tezacaftor and with ivacaftor, and ivacaftor (Trikafta®) for the treatment of cystic fibrosis. |
| CABOTEGRAVIR  Suspension for injection 600 mg in 3 mL  Apretude®  ViiV HEALTHCARE PTY LTD  (Review of positive PBAC recommendations not accepted by applicants) | Human immunodeficiency virus (HIV) prevention | To request the PBAC review its September 2023 recommendation that has not yet been accepted by the applicant. |
| LENACAPAVIR  Injection set containing 2 vials lenacapavir sodium solution for injection 463.5 mg in 1.5 mL and 2 disposable syringes  Sunlenca®  GILEAD SCIENCES PTY LIMITED  (Review of positive PBAC recommendations not accepted by applicants) | Human immunodeficiency virus (HIV) | To request the PBAC review its November 2023 recommendation that has not yet been accepted by the applicant. |
| PEMBROLIZUMAB  Solution concentrate for I.V. infusion 100 mg in 4 mL  Keytruda®   MERCK SHARP & DOHME (Australia) PTY LTD  (Review of positive PBAC recommendations not accepted by applicants) | Squamous cell carcinoma | To request the PBAC review its November 2023 recommendation that has not yet been accepted by the applicant. |
| PBAC advice on equitable access to glucagon-like peptide-1 (GLP-1) receptor agonist medicines for the treatment of obesity  Various forms and strengths  Various brands  (Other matters) | Obesity | To provide the PBAC with research findings and to seek its advice on ensuring equitable access to GLP-1 receptor agonist medicines for the treatment of obesity. |
| TENOFOVIR DISOPROXIL with EMTRICITABINE  Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg  CIPLA TENOFOVIR + EMTRICITABINE 300/200  CIPLA AUSTRALIA PTY LTD  TENOFOVIR/EMTRICITABINE 300/200 APX  TENOFOVIR/EMTRICITABINE 300/200 ARX  ARROTEX PHARMACEUTICALS PTY LTD  Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg  TENOFOVIR DISOPROXIL EMTRICITABINE VIATRIS 300/200  ALPHAPHARM PTY LTD  Tablet containing tenofovir disoproxil succinate 301 mg with emtricitabine 200 mg  TENOFOVIR/EMTRICITABINE SANDOZ 301/200  SANDOZ PTY LTD  (Other matters) | Pre-exposure prophylaxis (PrEP) against human immunodeficiency virus (HIV) infection | To request the PBAC consider whether increasing the number of repeats in the PBS listing for tenofovir disoproxil+ emtricitabine, for use as HIV PrEP, is appropriate. |

Version 5

Items added or amended

1. FUTIBATINIB (Lytgobi®) – Added
2. RECOMBINANT ZOSTER VACCINE (Shingrix®) – Form and indication amended
3. TENOFOVIR with EMTRICITABINE – Other matters – Added
4. TESTOSTERONE (AndroFeme 1®) – Form amended

Items added or amended previously

1. CABOTEGRAVIR (Apretude®) – Review of positive PBAC recommendations not accepted by applicants – Added
2. CETRORELIX (Femvi®) – PBS schedule amended
3. EFGARTIGIMOD ALFA (Vyvgart®) – PBS schedule amended
4. LENACAPAVIR (Sunlenca®) – Review of positive PBAC recommendations not accepted by applicants – Added
5. Life Saving Drugs Program (LSDP) medicines for Gaucher disease (type 1) – Added
6. Life Saving Drugs Program (LSDP) medicine for hereditary tyrosinaemia type 1 – Added
7. OSIMERTINIB (Tagrisso®) – To be considered at the September 2025 PBAC meeting
8. PBAC advice on equitable access to glucagon-like peptide-1 (GLP-1) receptor agonist medicines for the treatment of obesity (various brands) – Added
9. PEMBROLIZUMAB (Keytruda®)– Review of positive PBAC recommendations not accepted by applicants – Added
10. TESTOSTERONE (AndroFeme 1®) – Authority level amended