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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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| AMIVANTAMAB  Solution concentrate for I.V. infusion 350 mg in 7 mL   Rybrevant®  LAZERTINIB  Tablet 80 mg (as mesylate monohydrate) Tablet 240 mg (as mesylate monohydrate)  Lazcluze®   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 amivantamab and a General Schedule Authority Required (Telephone/Online) listing for lazertinib for the first line treatment of patients with epidermal growth factor receptor mutated locally advanced or metastatic (Stage IIIB-IV) NSCLC. |
| BULEVIRTIDE   Powder for injection 2 mg   Hepcludex®   GILEAD SCIENCES PTY LTD   (New PBS listing) | Chronic hepatitis D | Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of chronic hepatitis D. |
| CIPAGLUCOSIDASE ALFA  Powder for I.V. infusion 105 mg   Pombiliti®  MIGLUSTAT  Capsule 65 mg  Opfolda®   AMICUS THERAPEUTICS PTY LTD   (New PBS listing) | Late onset Pompe disease | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of late onset Pompe disease. |
| DABRAFENIB  Capsule 50 mg (as mesilate) Capsule 75 mg (as mesilate)  Tafinlar®  TRAMETINIB  Tablet 500 micrograms Tablet 2 mg  Mekinist®   NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LTD   (Change to existing listing) | Non-small cell lung cancer (NSCLC) | To request a General Schedule Authority Required (STREAMLINED) listing of dabrafenib in combination with trametinib for the treatment of adult patients with BRAF V600E mutation positive advanced or metastatic NSCLC. |
| DAPSONE   Tablet 50 mg   Dapsomed®   MEDSURGE HEALTHCARE PTY LTD   (New PBS listing) | Dermatitis herpetiformis Leprosy Actinomycotic mycetoma | To request a General Schedule Unrestricted Benefit listing of a new strength under the same conditions as the currently listed strengths of dapsone. |
| DARATUMUMAB   Solution for I.V. infusion 100 mg in 5 mL vial Solution for I.V. infusion 400 mg in 20 mL vial Solution for S.C. injection 1,800 mg in 15 mL vial   Darzalex®   JANSSEN-CILAG PTY LTD   (Change to existing listing) | Multiple myeloma | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (Telephone/Online) listing for the I.V. and S.C. formulations and a General Schedule Authority Required (Telephone/Online) listing for the S.C. formulation for use in combination with lenalidomide and dexamethasone for the treatment of transplant ineligible, newly diagnosed multiple myeloma. |
| DENOSUMAB   Injection 120 mg in 1 mL single use pre-filled syringe   Xgeva®   AMGEN AUSTRALIA PTY LIMITED   (New PBS listing) | Giant cell tumour of bone Bone metastases | To request General Schedule Authority Required (STREAMLINED) listings of a new form for the treatment of giant cell tumour of bone and bone metastases. |
| DUPILUMAB   Injection 200 mg in 1.14 mL single dose pre-filled pen Injection 300 mg in 2 mL single dose pre-filled pen   Dupixent®   SANOFI-AVENTIS AUSTRALIA PTY LTD   (New PBS listing) | Severe atopic dermatitis Uncontrolled severe asthma | To request the extension of two new forms to a General Schedule Authority Required listing for the treatment of severe atopic dermatitis in patients aged less than 12 years and a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of uncontrolled severe asthma in patients aged 6 to 11 years. |
| EFGARTIGIMOD ALFA   Solution concentrate of I.V. infusion 400 mg in 20 mL   Vyvgart®   ARGENX AUSTRALIA 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. |
| EFLORNITHINE   Tablet 192 mg (as hydrochloride)   Ifinwil®   NORGINE PTY LTD   (New PBS listing) | Neuroblastoma | To request a General Schedule Authority Required (Written) listing for the treatment of high-risk neuroblastoma. |
| ELACESTRANT   Tablet 86 mg (as dihydrochloride)  Tablet 345 mg (as dihydrochloride)   Orserdu®   A. MENARINI AUSTRALIA PTY LTD   (New PBS listing) | Estrogen receptor-positive (ER+) human epidermal growth factor receptor 2-negative (HER2-) locally advanced or metastatic breast cancer | To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of ER+/HER2- locally advanced or metastatic breast cancer in patients who have progressed following at least one line of endocrine therapy administered with a cyclin dependent kinase 4/6 inhibitor and have a confirmed estrogen receptor 1 variant. |
| ELAFIBRANOR   Tablet 80 mg   Iqirvo®   IPSEN PTY LTD   (New PBS listing) | Primary Biliary Cholangitis (PBC) | To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of PBC. |
| ELEXACAFTOR WITH TEZACAFTOR AND WITH IVACAFTOR, AND IVACAFTOR   Pack containing 56 tablets elexacaftor 100 mg with tezacaftor 50 mg and with ivacaftor 75 mg and 28 tablets ivacaftor 150 mg Pack containing 56 tablets elexacaftor 50 mg with tezacaftor 25 mg and with ivacaftor 37.5 mg and 28 tablets 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   (Change to existing listing) | Cystic fibrosis (CF) | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of CF patients aged 2 years or older who have at least one mutation in the CF transmembrane conductance regulator gene responsive to Trikafta® based on clinical and/or in vitro assay data. |
| 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) | Resubmission 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 lines of therapy. |
| ESTETROL WITH DROSPIRENONE   Pack containing 24 tablets estetrol 14.2 mg with drospirenone 3 mg and 4 inert tablets   Nextstellis®   MAYNE PHARMA INTERNATIONAL PTY LTD   (New PBS listing) | Contraception | To request a General Schedule unrestricted listing. |
| FARICIMAB   Solution for intravitreal injection 21 mg in 0.175 mL (120 mg per mL) pre-filled syringe   Vabysmo®   ROCHE PRODUCTS PTY LTD   (New PBS listing) | Macular oedema secondary to retinal vein occlusion (RVO) | To request a General Schedule Authority Required (Written) listing for the initial treatment and an Authority Required (STREAMLINED) listing for the continuing treatment of a new form for macular oedema secondary to RVO. |
| FEZOLINETANT   Tablet 45 mg   Veoza®   ASTELLAS PHARMA AUSTRALIA PTY LTD   (New PBS listing) | Moderate to severe menopause-related vasomotor symptoms (VMS) | To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of moderate to severe menopause-related VMS. |
| FUTIBATINIB   Tablet 4 mg   Lytgobi®   TAIHO PHARMA OCEANIA PTY LTD   (New PBS listing) | Bile duct cancer (cholangiocarcinoma) | To request a General Schedule Authority Required (STREAMLINED) listing 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. |
| GEMCITABINE   Solution for injection 1 g (as hydrochloride) in 25 mL Solution for injection 2 g (as hydrochloride) in 50 mL   Gemcitabine Sandoz®   SANDOZ PTY LTD   (New PBS listing) | Various cancers | To request Section 100 (Efficient Funding of Chemotherapy Program) Unrestricted Benefit listings of new forms of gemcitabine. |
| INFLIXIMAB   Solution 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 AUSTRALIA PTY LTD   (Change to existing listing) | Severe active rheumatoid arthritis Ankylosing spondylitis Severe psoriatic arthritis Severe chronic plaque psoriasis Severe Crohn disease,  Complex refractory fistulising Crohn Disease Moderate to severe ulcerative colitis | To request an amendment to the restriction level from Authority Required (Telephone/Online) to Authority Required (STREAMLINED) for the continuing treatment of the currently listed indications of Remsima® SC. |
| INFLIXIMAB   Powder for I.V. infusion 100 mg   Ixifi®   PFIZER AUSTRALIA PTY LTD   (New PBS listing) | Severe active rheumatoid arthritis Ankylosing spondylitis Severe psoriatic arthritis Severe chronic plaque psoriasis Severe Crohn disease,  Complex refractory fistulising Crohn Disease Moderate to severe ulcerative colitis | To request Section 100 (Highly Specialised Drugs Program) Authority Required listings of a new infliximab biosimilar under the same conditions as other biosimilar brands of infliximab. |
| IVACAFTOR   Sachet containing granules 13.4 mg  Sachet containing granules 25 mg  Sachet containing granules 50 mg  Sachet containing granules 75 mg  Tablet 150 mg   Kalydeco®   VERTEX PHARMACEUTICALS (AUSTRALIA) PTY LTD   (New PBS listing) | Cystic fibrosis (CF) | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of CF patients aged 1 to 4 months who have a gating mutation or at least one mutation in the CF transmembrane conductance regulator gene. |
| LUMASIRAN   Solution for subcutaneous injection 94.5 mg in 0.5 mL   Oxlumo®   MEDISON PHARMA AUSTRALIA PTY LTD   (New PBS listing) | Primary hyperoxaluria type 1 | To request a General Schedule Authority Required (STREAMLINED) listing for primary hyperoxaluria type 1. |
| MIDOSTAURIN   Capsule 25 mg   Rydapt®   NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LTD   (Change to existing listing) | Advanced systemic mastocytosis | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of adult patients with advanced systemic mastocytosis. |
| MOGAMULIZUMAB   Solution concentrate for I.V. infusion 20 mg in 5 mL   Poteligeo®   KYOWA KIRIN AUSTRALIA PTY LTD   (New PBS listing) | Cutaneous T-cell lymphoma (CTCL) | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Written) listing for the treatment of relapsed or refractory CTCL (mycosis fungoides or Sezary syndrome) who have previously been treated with at least one prior systemic therapy. |
| NATALIZUMAB   Solution concentrate for I.V. infusion 300 mg in 15 mL   Tyruko®   SANDOZ PTY LTD   (New PBS listing) | Relapsing-remitting multiple sclerosis (RRMS) | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing of a natalizumab biosimilar for the treatment of RRMS under the same conditions as its reference biologic. |
| 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) | Resubmission 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. |
| 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) | Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of PFIC. |
| OMALIZUMAB   Injection 75 mg in 0.5 mL single dose pre-filled syringe Injection 150 mg in 1 mL single dose pre-filled syringe   Omlyclo®   CELLTRION HEALTHCARE AUSTRALIA PTY LTD   (New PBS listing) | Uncontrolled severe asthma Uncontrolled severe allergic asthma Severe chronic spontaneous urticaria | To request Section 100 (Highly Specialised Drugs Program) Authority Required listings of an omalizumab biosimilar for the treatment of uncontrolled severe asthma, uncontrolled severe allergic asthma, and severe chronic spontaneous urticaria, under the same conditions as its reference biologic. |
| OMALIZUMAB   Injection 75 mg in 0.5 mL single dose pre-filled syringe Injection 150 mg in 1 mL single dose pre-filled syringe Injection 300 mg in 2 mL single dose pre-filled syringe Injection 75 mg in 0.5 mL single dose pre-filled pen  Injection 150 mg in 1 mL single dose pre-filled pen Injection 300 mg in 2 mL single dose pre-filled pen   Xolair®   NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED   (New PBS listing) | Uncontrolled severe asthma Uncontrolled severe allergic asthma Severe chronic spontaneous urticaria | To request Section 100 (Highly Specialised Drugs Program) Authority Required listings of a new strength and new forms of omalizumab for the treatment of uncontrolled severe asthma, uncontrolled severe allergic asthma, and severe chronic spontaneous urticaria. |
| OMAVELOXOLONE   Capsule 50 mg   Skyclarys®   BIOGEN AUSTRALIA PTY LTD   (New PBS listing) | Friedreich’s ataxia | To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of Friedreich’s ataxia in adults and adolescents aged 16 years and older. |
| PALOPEGTERIPARATIDE   Solution for subcutaneous injection 168 micrograms in 0.56 mL pre-filled pen Solution for subcutaneous injection 294 micrograms in 0.98 mL pre-filled pen Solution for subcutaneous injection 420 micrograms in 1.4 mL pre-filled pen   Yorvipath®   SPECIALISED THERAPEUTICS PHARMA PTY LTD   (New PBS listing) | Chronic hypoparathyroidism | To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of chronic hypoparathyroidism. |
| PEMBROLIZUMAB   Solution concentrate for I.V. infusion 100 mg in 4 mL   Keytruda®   MERCK SHARP & DOHME (AUSTRALIA) PTY LTD   (Change to existing listing) | Cervical cancer | To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of high risk, locally advanced cervical cancer. |
| PERTUZUMAB   Solution for I.V. infusion 420 mg in 14 mL   Perjeta®   ROCHE PRODUCTS PTY LTD   (Change to existing listing) | Human epidermal growth factor receptor 2-positive (HER2+) locally advanced, inflammatory or early stage breast cancer | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (Telephone/Online) listing, in combination with trastuzumab and chemotherapy, for the neoadjuvant treatment of HER2+ locally advanced, inflammatory or early stage breast cancer. |
| POLATUZUMAB VEDOTIN   Powder for I.V. infusion 30 mg Powder for I.V. infusion 140 mg   Polivy®   ROCHE PRODUCTS PTY LTD   (New PBS listing) | Diffuse large B-cell lymphoma (DLBCL) | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing, in combination with rituximab, cyclophosphamide, doxorubicin and prednisone, for the treatment of previously untreated DLBCL. |
| 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 AUSTRALIASIA PTY LTD   (Change to existing listing) | Generalised myasthenia gravis (gMG) | Resubmission 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. |
| ROZANOLIXIZUMAB   Solution for subcutaneous infusion 280 mg in 2 mL (140 mg per mL)   Rystiggo®   UCB AUSTRALIA 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. |
| RUXOLITINIB   Tablet 5 mg Tablet 10 mg Tablet 15 mg Tablet 20 mg   Jakavi®   NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LTD   (Change to existing listing) | Polycythemia vera (PV) | Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of adult patients with PV who are resistant to or intolerant of hydroxycarbamide (hydroxyurea). |
| SACITUZUMAB GOVITECAN   Powder for injection 180 mg   Trodelvy®   GILEAD SCIENCES PTY LIMITED   (Change to existing listing) | Breast cancer | To request a definition for human epidermal growth factor receptor 2 (HER2) status be added to the clinical criteria for the initial treatment of unresectable locally advanced or metastatic triple-negative breast cancer. |
| SOTATERCEPT   Powder for subcutaneous injection 45 mg (50 mg per mL) Powder for subcutaneous injection 60 mg (50 mg per mL)   Winrevair®   MERCK SHARP & DOHME (AUSTRALIA) PTY LTD   (New PBS listing) | Pulmonary arterial hypertension (PAH) | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Telephone/Online) listing as add on therapy for the treatment of Group 1 PAH. |
| TARLATAMAB   Powder for injection 10 mg   Imdelltra®   AMGEN AUSTRALIA PTY LTD   (New PBS listing) | Small cell lung cancer | To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the third-line plus treatment of extensive-stage small cell lung cancer. |
| TEPROTUMUMAB   Powder for I.V. infusion 500 mg   Tepezza®   AMGEN AUSTRALIA PTY LTD   (New PBS listing) | Thyroid eye disease (TED) | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of active, moderate-to-severe TED. |
| TORIPALIMAB   Solution concentrate for I.V. infusion 240 mg in 6 mL (40 mg per mL)   Zytorvi®   DR REDDY'S LABORATORIES AUSTRALIA PTY LTD   (New PBS listing) | Nasopharyngeal carcinoma | To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of recurrent or metastatic nasopharyngeal carcinoma. |
| USTEKINUMAB   Injection 45 mg in 0.5 mL single use pre-filled syringe Injection 90 mg in 1 mL single use pre-filled syringe Solution concentrate for I.V. infusion 130 mg in 26 mL (5 mg per mL)   Epyztek®   SAMSUNG BIOEPIS AU PTY LTD   (New PBS listing) | Severe chronic plaque psoriasis (CPP) Severe psoriatic arthritis (PsA) Severe Crohn disease (CD) Complex refractory fistulising CD (fCD) | To request General Schedule and Section 100 (Highly Specialised Drugs Program) listings of an ustekinumab biosimilar for the treatment of CPP, PsA, CD, and fCD. |
| 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 PTY LTD   (New PBS listing) | Generalised myasthenia gravis (gMG) | Resubmission 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. |
| ZOLBETUXIMAB   Powder for I.V. infusion 100 mg (20 mg per mL)   Vyloy®   ASTELLAS PHARMA AUSTRALIA PTY LTD   (New PBS listing) | Gastric or gastroesophageal junction (G/GOJ) cancer | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the first-line treatment of locally advanced unresectable or metastatic epidermal growth factor receptor 2-negative G/GOJ adenocarcinoma. |
| ELEXACAFTOR WITH TEZACAFTOR AND WITH IVACAFTOR, 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  (Sub-committee report DUSC analysis)  REMOVED | Cystic Fibrosis | To assess the utilisation of PBS listed elexacaftor with tezacaftor and with ivacaftor, and ivacaftor (Trikafta®) for the treatment of cystic fibrosis. |
| FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL  100mcg/62.5mcg/25mcg 200mcg/62.5mcg/25mcg  Trelegy Ellipta®  GLAXOSMITHKLINE AUSTRALIA PTY LTD  (Sub-committee report DUSC analysis)  TO BE CONSIDERED AT MAY 2025 PBAC MEETING | Severe Asthma | To assess the utilisation of PBS listed fluticasone furoate + umeclidinium + vilanteroal (Trelegy Ellipta®) and single inhaler triple therapies for the treatment of severe asthma. |
| MEDICINES FOR GASTROINTESTINAL STROMAL TUMOUR  All brands and strengths  Various sponsors  (Sub-committee report DUSC Analysis)  TO BE CONSIDERED AT MAY 2025 PBAC MEETING | Gastrointestinal Stromal Tumour | To assess the utilisation of PBS listed medicines for the treatment of gastrointestinal stromal tumour. |
| ZANUBRUTINIB  Capsule 80 mg  Brukinsa®  BEIGENE AUS PTY LTD  (Sub-committee report DUSC analysis)  TO BE CONSIDERED AT MAY 2025 PBAC MEETING | Waldenström Macroglobulinaemia | To assess the utilisation of PBS listed zanubrutinb for the treatment of Waldenström Macroglobulinaemia. |
| ALIROCUMAB  Injection 300 mg in 2 mL single dose autoinjector  Praluent®   SANOFI-AVENTIS AUSTRALIA PTY LTD  (Review of positive PBAC recommendations not accepted by applicants) | Familial heterozygous hypercholesterolaemia Non-familial hypercholesterolaemia | To request the PBAC review its March 2023 recommendation that has not yet been accepted by the applicant. |
| BEVACIZUMAB  Solution for I.V. infusion 100 mg in 4 mL  Solution for I.V. infusion 400 mg in 16 mL  Zirabev®  PFIZER AUSTRALIA PTY LTD  (Review of positive PBAC recommendations not accepted by applicants) | Various cancers | To request the PBAC review its July 2020 recommendation that has not yet been accepted by the applicant. |
| IXEKIZUMAB  Injection 80 mg in 1 mL single dose pre-filled pen  Taltz®  ELI LILLY AUSTRALIA PTY LTD  (Review of positive PBAC recommendations not accepted by applicants) | Non-radiographic axial spondyloarthritis | To request the PBAC review its November 2021 recommendation that has not yet been accepted by the applicant. |
| SECUKINUMAB  Injection 75 mg in 0.5 mL pre-filled syringe  Injection 150 mg in 1 mL pre-filled pen  Injection 300 mg in 2 mL pre-filled syringe  Injection 300 mg in 2 mL pre-filled pen  Cosentyx®  NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LTD  (Review of positive PBAC recommendations not accepted by applicants) | Paediatric psoriasis | To request the PBAC review its November 2021 recommendation that has not yet been accepted by the applicant. |

Version 3

Items added or amended

1. ALIROCUMAB (Praluent®) – Review of positive PBAC recommendations not accepted by applicants – Added
2. BEVACIZUMAB (Zirabev®) – Review of positive PBAC recommendations not accepted by applicants – Added
3. EFLORNITHINE (Ifinwil®) – Purpose of submission amended
4. ELEXACAFTOR WITH TEZACAFTOR AND WITH IVACAFTOR, AND IVACAFTOR (Trikafta®) – Removed
5. ELRANATAMAB (Elrexfio®) – Purpose of submission amended
6. FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL (Trelegy Ellipta®) – To be considered at May 2025 PBAC meeting
7. IXEKIZUMAB (Taltz®) – Review of positive PBAC recommendations not accepted by applicants – Added
8. MEDICINES FOR GASTROINTESTINAL STROMAL TUMOUR (All brands) – To be considered at May 2025 PBAC meeting
9. SECUKINUMAB (Cosentyx®) – Review of positive PBAC recommendations not accepted by applicants – Added
10. ZANUBRUTINIB (Brukinsa®) – To be considered at May 2025 PBAC meeting

Items added or amended previously

1. AMIVANTAMAB (Rybrevant®), LAZERTINIB (Lazcluze®) – Drug name, form, and submission purpose amended
2. CIPAGLUCOSIDASE ALFA (Pombiliti®), MIGLUSTAT (Opfolda®) – Drug name amended
3. DABRAFENIB (Tafinlar®), TRAMETINIB (Mekinist®) – Drug name amended
4. ELEXACAFTOR WITH TEZACAFTOR AND WITH IVACAFTOR, AND IVACAFTOR (Trikafta®) – Submission purpose amended