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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**  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.) |
| --- | --- | --- |
| ABEMACICLIB  Tablet 50 mg Tablet 100 mg Tablet 150 mg  Verzenio®  ELI LILLY AUSTRALIA PTY LTD  (Change to existing listing) | Hormone receptor positive (HR+) human epidermal growth factor receptor 2 negative (HER2-) breast cancer | To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of HR+ HER2- lymph node positive, invasive, resected early breast cancer at high risk of disease recurrence. |
| ADALIMUMAB  Injection 40 mg in 0.4 mL pre-filled syringe Injection 40 mg in 0.4 mL pre-filled pen  Hadlima®  ORGANON PHARMA PTY LTD  (New listing) | Severe Crohn disease Moderate to severe ulcerative colitis Severe active juvenile idiopathic arthritis  Complex refractory fistulising Crohn disease Severe active rheumatoid arthritis Severe psoriatic arthritis Ankylosing spondylitis  Severe chronic plaque psoriasis Moderate to severe hidradenitis suppurativa | To request a General Schedule Authority Required (Written) listing of HADLIMA® 40 mg in 0.4 mL pre-filled syringe and 40 mg in 0.4 mL pre-filled pen under the same circumstances as the PBS-listed reference biologic HUMIRA® for all indications for which HADLIMA® 40 mg in 0.8 mL pre-filled syringe and 40 mg in 0.8 mL pre-filled pen are currently listed on the PBS. |
| APREMILAST  Tablet 30 mg  Pack containing 4 tablets 10 mg, 4 tablets 20 mg and 19 tablets 30 mg  Otezla®  AMGEN AUSTRALIA PTY LIMITED  (Change to existing listing) | Chronic plaque psoriasis (CPP) | To request a change in the General Schedule Authority Required (STREAMLINED) listing for the treatment of severe CPP to allow treatment initiation by additional medical practitioner types. |
| BUDESONIDE + FORMOTEROL  Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 60 doses  Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses  Bufomix Easyhaler®  ORION PHARMA (AUS) PTY LIMITED  (New listing) | Asthma  Chronic obstructive pulmonary disease (COPD) | To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of asthma and COPD on the basis of bioequivalence to SYMBICORT TURBUHALER®. |
| CABOZANTINIB  Tablet 20 mg Tablet 40 mg Tablet 60 mg  Cabometyx®  IPSEN PTY LTD  (Change to existing listing) | Differentiated thyroid cancer (DTC) | To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of locally advanced or metastatic DTC in patients who have progressed during or after prior vascular endothelial growth factor-targeted therapy. |
| CEMIPLIMAB  Solution for I.V. infusion 350 mg in 7 mL  Libtayo®  SANOFI-AVENTIS AUSTRALIA PTY LTD  (Change to existing listing) | Non-small cell lung cancer (NSCLC) | To request a Section 100 (Efficicent Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing to be used with platinum doublet chemotherapy as a first line treatment of adult patients with Stage IV (metastatic) NSCLC. |
| CHLORMETHINE HYDROCHLORIDE  Gel 160 microgram per g, 60 g   Ledaga®  JUNIPER BIOLOGICS PTY LTD  (New listing) | Mycosis fungoides-type cutaneous T-cell lymphoma (MF-type CTCL) | To request a General Schedule Authority Required (Telephone/Online) listing for the topical treatment of MF-type CTCL. |
| CLADRIBINE  Tablet 10 mg  Mavenclad®  MERCK HEALTHCARE PTY LTD  (Change to existing listing) | Relapsing-remitting multiple sclerosis (RRMS) | To request a revision to the equi-effective doses of cladribine versus fingolimod for the treatment of RRMS. |
| DAUNORUBICIN WITH CYTARABINE  Powder for I.V infusion containing daunorubicin 44 mg and cytarabine 100 mg  Vyxeos®  Jazz Pharmaceuticals ANZ Pty Ltd  (New listing) | Acute myeloid leukaemia | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for the treatment of therapy-related acute myeloid leukaemia (t-AML) and acute myeloid leukaemia with myelodysplasia-related changes (AML-MRC). |
| DIFELIKEFALIN  Solution for I.V. injection 50 micrograms in 1 mL vial  Korsuva®  VIFOR PHARMA PTY LIMITED  (New listing) | Chronic kidney disease associated pruritus | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Telephone/Online) listing for the treatment of moderate-to-severe pruritus associated with chronic kidney disease. |
| DOSTARLIMAB  Solution concentrate for I.V. infusion 500 mg in 10 mL  Jemperli®  GLAXOSMITHKLINE AUSTRALIA PTY LTD  (New listing) | Endometrial cancer | To request a Section 100 (EFC) Authority Required (STREAMLINED) listing for use in combination with platinum-containing chemotherapy for the treatment of primary advanced or first recurrent endometrial cancer. |
| DUPILUMAB  Injection 200 mg in 1.14 mL single dose pre-filled syringe  Injection 300 mg in 2 mL single dose pre-filled syringe  Dupixent®  SANOFI-AVENTIS AUSTRALIA PTY LTD  UPADACITINIB  Tablet 15 mg  Tablet 30 mg  Rinvoq®  ABBVIE PTY LTD  (Matters outstanding) | Severe atopic dermatitis (AD) | PBAC consideration of the cost-effectiveness of dupilumab and upadacitinib for severe AD. |
| EDARAVONE  Solution concentrate for injection 30 mg in 20 mL  Radicava®  TEVA PHARMA AUSTRALIA PTY LTD  (New listing) | Amyotrophic lateral sclerosis (ALS) | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Telephone/Online) listing for the treatment of ALS. |
| ELTROMBOPAG  Tablet 25 mg Tablet 50 mg  Revolade®  HAEMATOLOGY SOCIETY OF AUSTRALIA AND NEW ZEALAND  (Change to existing listing) | Aplastic anaemia (AA) | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of severe AA. |
| EMPAGLIFLOZIN  Tablet 10 mg  Jardiance®  BOEHRINGER INGELHEIM PTY LTD  (Change to existing listing) | Chronic kidney disease | To request a General Schedule Authority Required (STREAMLINED) listing for chronic kidney disease. |
| FLUTICASONE PROPIONATE + SALMETEROL  Powder for oral inhalation in breath actuated device containing fluticasone propionate 250 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses Powder for oral inhalation in breath actuated device containing fluticasone propionate 500 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses   Salflumix Easyhaler®  ORION PHARMA (AUS) PTY LIMITED  (New listing) | Asthma  Chronic obstructive pulmonary disease (COPD) | To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of asthma and COPD |
| ICOSAPENT ETHYL  Capsule 1 g  Vazkepa®  SEQIRUS (AUSTRALIA) PTY LTD  (New listing) | Atherosclerotic cardiovascular disease with elevated triglycerides | To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of atherosclerotic cardiovascular disease with elevated triglycerides. |
| IMATINIB, DASATINIB, NILOTINIB, PONATINIB, ASCIMINIB  All brands and strengths  Various sponsors  (Other matters)  To be considered at a future PBAC meeting | Chronic myeloid leukaemia (CML) | For the PBAC to consider updating the restriction wording for tyrosine kinase inhibitors (TKIs) in CML. |
| IVACAFTOR  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 listing) | Cystic fibrosis (CF) with the CF transmembrane conductance regulator (CFTR) gene mutation | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of (i) CF patients aged 4 to 12 months with a gating (Class III) CFTR gene mutation; (ii) CF patients aged 4 months or older with at least one CFTR gene mutation shown to be responsive to ivacaftor potentiation. |
| LENACAPAVIR  Tablet 300 mg  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  (New listing) | Human immunodeficiency virus (HIV) | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of multidrug resistant HIV. |
| LENALIDOMIDE  Capsule 20 mg  Lenalide®  JUNO PHARMACEUTICALS PTY LTD  (New listing) | Multiple myeloma (MM) Myelodysplastic syndromes (MDS) Mantle cell lymphoma (MCL) | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Telephone/Online) listing of a new strength under the same conditions and for the same population as the currently listed strengths. |
| MARIBAVIR  Tablet 200 mg  Livtencity®  TAKEDA PHARMACEUTICALS AUSTRALIA PTY LTD  (New listing) | Post-transplant cytomegalovirus (CMV) | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for treatment of post-transplant CMV infection and disease that is refractory, resistant or intolerant to one or more prior therapies. |
| MAVACAMTEN  Capsule 2.5 mg Capsule 5 mg Capsule 10 mg Capsule 15 mg  Camzyos®  BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD  (New listing) | Hypertrophic cardiomyopathy | Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy. |
| MEDROXYPROGESTERONE ACETATE  Suspension for injection 150 mg in 1 mL pre-filled syringe  Depo-Provera®  PFIZER AUSTRALIA PTY LTD  (New listing) | Unrestricted benefit | To request a General Schedule unrestricted listing for a pre-filled syringe that will replace the currently listed vial. |
| MENINGOCOCCAL VACCINE  Injection 0.5 mL  Menveo®  GLAXOSMITHKLINE AUSTRALIA PTY LTD  (New listing) | Prevention of invasive meningococcal diseases (IMDs) | To request a National Immunisation Program listing for adolescents for the prevention of IMDs caused by Neisseria meningitidis serogroups A, C, W-135 and Y |
| MIDAZOLAM  Oromucosal solution in pre-filled syringe 2.5 mg in 0.25 mL Oromucosal solution in pre-filled syringe 5 mg in 0.5 mL Oromucosal solution in pre-filled syringe 7.5 mg in 0.75 mL Oromucosal solution in pre-filled syringe 10 mg in 1 mL  Zyamis®  CLINECT PTY LTD  (Other matters) | Generalised convulsive status epilepticus (GCSE) | To request consideration of revised financial estimates and risk share proposal for a General Schedule Authority required (Telephone/Online) listing for the treatment of GCSE. |
| MOLNUPIRAVIR  Capsule 200 mg  Lagevrio®  MERCK SHARP & DOHME (AUSTRALIA) PRT LTD  (Matters outstanding) | Mild to moderate SARS-CoV-2 infection | To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of high risk patients with mild to moderate SARS-CoV-2 infection. |
| NIRMATRELVIR AND RITONAVIR  Pack containing 4 tablets nirmatrelvir 150 mg and 2 tablets ritonavir 100 mg, 5  Paxlovid®  PFIZER AUSTRALIA PTY LTD  (Change to existing listing) | SARS-CoV-2 infection | To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of SARS-CoV-2 infection in people who are at increased risk of severe disease. |
| NIVOLUMAB  Injection concentrate for I.V. infusion 40 mg in 4 mL  Injection concentrate for I.V. infusion 100 mg in 10 mL  Opdivo®  BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD  (Change to existing listing) | Muscle invasive urothelial carcinoma (MIUC) | To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for the adjuvant treatment of high-risk MIUC. |
| OLAPARIB  Tablet 100 mg Tablet 150 mg  Lynparza®  ASTRAZENECA PTY LTD  (Change to existing listing) | Metastatic castration-resistant prostate cancer (mCRPC) | To request a General Schedule Authority Required (Telephone/Online) listing for the first line treatment of mCRPC in patients with a Class 4 or 5 Breast Cancer Gene 1 (BRCA1) or BRCA2 mutation who have not received prior treatment with a novel hormonal agent. |
| OLAPARIB  Tablet 100 mg Tablet 150 mg  Lynparza®  ASTRAZENECA PTY LTD  (Change to existing listing) | Human epidermal growth factor receptor 2 (HER2)-negative early breast cancer | To request a General Schedule Authority Required (Telephone/Online) listing for patients with HER2-negative high risk early breast cancer with a confirmed germline Breast Cancer Gene 1 (BRCA1) or BRCA2 mutation. |
| OSIMERTINIB  Tablet 40 mg Tablet 80 mg  Tagrisso®  ASTRAZENECA PTY LTD  (Change to existing listing) | Non-small cell lung cancer (NSCLC) | To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of Stage IB to IIIA epidermal growth factor receptor mutation positive NSCLC as adjuvant therapy after surgical resection. |
| OXYBUTYNIN  Transdermal patches 36 mg, 8   Oxytrol®  THERAMEX AUSTRALIA PTY LTD  (Change to existing listing) | Detrusor overactivity in patients unable to tolerate or unable to swallow oral oxybutynin | To request consideration of whether oxybutynin 3.9 mg transdermal patch satisfies the criteria to be classified an ‘exempt item’ as described by Section 84AH of the National Health Act 1953. |
| PEMBROLIZUMAB   Solution concentrate for I.V. infusion 100 mg in 4 mL  Keytruda®  MERCK SHARP & DOHME (AUSTRALIA) PTY LTD  (Change to existing listing) | Squamous cell carcinoma (SCC) | To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of metastatic or locally advanced cutaneous SCC that is not curative by surgery or radiation. |
| PNEUMOCOCCAL CONJUGATE VACCINE, 20-VALENT   0.5 mL pre-filled syringe  Prevenar 20®  PFIZER AUSTRALIA PTY LTD  (New listing) | Prevention of pneumococcal disease | To request an NIP listing for paediatric populations. |
| RISANKIZUMAB  Injection 150 mg in 1 mL pre-filled syringe Injection 150 mg in 1 mL pre-filled pen  Skyrizi®  ABBVIE PTY LTD  (Change to existing listing) | Chronic plaque psoriasis (CPP) | To request a General Schedule Authority Required (Written) listing for the treatment of severe CPP. |
| SACITUZUMAB GOVITECAN  Powder for injection 180 mg  Trodelvy®  GILEAD SCIENCES PTY LIMITED  (Change to existing listing) | Hormone receptor-positive (HR+) human epidermal growth factor receptor-2 negative (HER2-) advanced or metastatic breast cancer | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of adult patients with unresectable locally advanced or metastatic HR+, HER2- breast cancer, who have previously received at least two systemic therapies, one of which may have been in the neoadjuvant/adjuvant setting. |
| SECUKINUMAB  Solution for injection 300 mg in 2 mL pre-filled syringe Solution for injection 150 mg in 1 mL pre-filled syringe Solution for injection 150 mg in 1 mL pre-filled pen Solution for injection 300 mg in 2 mL pre-filled pen  Cosentyx®  NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED  (Change to existing listing) | Hidradenitis suppurativa (HS) | Resubmission to request a General Schedule Authority Required (Written) listing for the treatment of HS. |
| SEMAGLUTIDE  Injection 0.25 mg in 0.5 mL pre-filled single dose pen Injection 0.5 mg in 0.5 mL pre-filled single dose pen Injection 1.0 mg in 0.5 mg pre-filled single dose pen Injection 1.7 mg in 0.75 mL pre-filled single dose pen Injection 2.4 mg in 0.75 mL pre-filled single dose pen  Wegovy®  NOVO NORDISK PHARMACEUTICALS PTY. LIMITED  (New listing) | Severe obesity | To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of severe obesity despite prior participation in an appropriate lifestyle-based weight management intervention. |
| TERIPARATIDE  Injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled cartridge  Teriparatide Lupin®  GENERIC HEALTH PTY LTD  (New listing) | Osteoporosis | To request a General Schedule Authority Required (STREAMLINED) listing under the same conditions as the currently listed brand TERROSA®. |
| TERIPARATIDE  Injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled pen  Terrosa®  GEDEON RICHTER AUSTRALIA PTY LTD  (New listing) | Osteoporosis | To request a General Schedule Authority Required (STREAMLINED) listing for a pre-filled pen under the same conditions as the currently listed cartridge presentation. |
| TISLELIZUMAB  Solution concentrate for injection 100 mg in 10 mL  Tevimbra®  BEIGENE AUS PTY LTD  (New listing)  To be considered at a future PBAC meeting | Non-small cell lung cancer (NSCLC) | To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first-line treatment of patients with Stage IV (metastatic) NSCLC. |
| TRASTUZUMAB DERUXTECAN  Powder for I.V. infusion 100 mg  Enhertu®  ASTRAZENECA PTY LTD  (New listing) | Human epidermal growth factor receptor 2 (HER2)-low breast cancer | To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for the treatment of patients with HER2-low unresectable or metastatic breast cancer. |
| VARICELLA ZOSTER VIRUS RECOMBINANT VACCINE  Injection 1 vial & adjuvant substance diluent 0.5 mL vial  Shingrix®  GLAXOSMITHKLINE AUSTRALIA PTY LTD  (Matters outstanding) | Herpes zoster virus | To request consideration of the population that was deferred at the March 2023 PBAC meeting: broader population of immunocompromised individuals aged ≥ 18 years at increased risk of herpes zoster. |
| ADALIMUMAB  Injection 40 mg in 0.8 mL pre-filled pen Injection 40 mg in 0.8 mL pre-filled syringe  Hulio®  Alphapharm Pty Ltd  (Review of positive PBAC recommendations not accepted by applicants) | Severe Crohn disease Ulcerative colitis Juvenile idiopathic arthritis  Complex refractory fistulising Crohn disease Rheumatoid arthritis Psoriatic arthritis Ankylosing spondylitis Chronic plaque psoriasis Hiradenitis suppurative | - |
| 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) | Metastatic colorectal cancer Advanced, metastatic or recurrent non-squamous non-small lung cancer Relapsed or recurrent glioblastoma Epithelial ovarian, fallopian tube or primary peritoneal cancer Cervical cancer | - |
| ETANERCEPT  Injection 50 mg in 1 mL single use pre-filled syringe  Rymti®  Alphapharm Pty Ltd  (Review of positive PBAC recommendations not accepted by applicants) | Rheumatoid arthritis Plaque psoriasis  Ankylosing spondylitis  Psoriatic arthritis  Juvenile idiopathic arthritis  Paediatric plaque psoriasis | - |
| INSULIN ASPART  Injection (human analogue), cartridge 100 units per mL, 3 mL Injection (human analogue), pre-filled pen, 100 units per mL, 3 mL  Truvelog® Truvelog Solostar®  Sanofi-Aventis Australia Pty Ltd  (Review of positive PBAC recommendations not accepted by applicants) | Diabetes mellitus | - |
| 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 | - |
| MELATONIN  Tablet 1 mg Tablet 5 mg  Slenyto®  Aspen Pharmacare Australia Pty Ltd  (Review of positive PBAC recommendations not accepted by applicants) | Smith-Magenis syndrome | - |
| RISANKIZUMAB  Injection 150 mg in 1 mL pre-filled pen Injection 150 mg in 1 mL pre-filled syringe  Skyrizi®  AbbVie Pty Ltd  (Review of positive PBAC recommendations not accepted by applicants) | Severe chronic plaque psoriasis | - |
| 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 |  |
| OMALIZUMAB  Injection 150 mg in 1 mL single dose pre-filled syringe   Xolair®  NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED  (Systematic literature review to supplement DUSC Analysis) | Chronic spontaneous urticaria (CSU) | To consider the findings of a systematic literature review of the most recent comparative clinical evidence for omalizumab and cyclosporin for the treatment of CSU, including the equi-effective dose, for comparison with the evidence previously considered by the PBAC. |
| APREMILAST  Tablet 30 mg  Pack containing 4 tablets 10 mg, 4 tablets 20 mg and 19 tablets 30 mg  Otezla®  AMGEN AUSTRALIA PTY LIMITED  (Sub-committee report DUSC Analysis) | Severe chronic plaque psoriasis | To assess the utilisation of apremilast for the treatment of severe chronic plaque psoriasis |
| DUPILUMAB  Injection 200 mg in 1.14 mL single dose pre-filled syringe Injection 300 mg in 2 mL single dose pre-filled syringe  Dupixent®  SANOFI-AVENTIS AUSTRALIA PTY LTD  (Sub-committee report DUSC Analysis) | Chronic severe atopic dermatitis | To assess the utilisation of dupilumab for the treatment of chronic severe atopic dermatitis |
| LISDEXAMFETAMINE  Capsule containing lisdexamfetamine dimesilate 20 mg Capsule containing lisdexamfetamine dimesilate 30 mg Capsule containing lisdexamfetamine dimesilate 40 mg Capsule containing lisdexamfetamine dimesilate 50 mg Capsule containing lisdexamfetamine dimesilate 60 mg Capsule containing lisdexamfetamine dimesilate 70 mg  Vyvanse®  TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD.  (Sub-committee report DUSC Analysis) | Attention deficit hyperactivity disorder | To assess the utilisation of lisdexamfetamine for the treatment of attention deficit hyperactivity disorder |
| VENETOCLAX  Pack containing 14 tablets venetoclax 10 mg and 7 tablets venetoclax 50 mg and 7 tablets venetoclax 100 mg and 14 tablets venetoclax 100 mg Tablet 100 mg  Venclexta®  ABBVIE PTY LTD  (Sub-committee report DUSC Analysis) | Chronic lymphocytic leukaemia or small lymphocytic lymphoma | To assess the utilisation of venetoclax for the treatment of chronic lymphocytic leukaemia or small lymphocytic lymphoma |

Version 6

Items added or amended

* + - * 1. BUDESONIDE + FORMOTEROL (Bufomix Easyhaler®) – Drug form amended
        2. CHLORMETHINE HYDROCHLORIDE (Ledaga®) – Drug form amended
        3. FLUTICASONE PROPIONATE + SALMETEROL (Salflumix Easyhaler®) – Drug form amended
        4. IVACAFTOR (Kalydeco®) – Drug form amended
        5. LENACAPAVIR (Sunlenca®) – Drug form amended
        6. OXYBUTYNIN (Oxytrol®) – Drug form amended

Items added or amended previously

* + - * 1. ADALIMUMAB (Hulio®) – Review of positive PBAC recommendations not accepted by applicants – Added
        2. BEVACIZUMAB (Zirabev®) – Review of positive PBAC recommendations not accepted by applicants - Added
        3. DURVALUMAB (Infinzi®) – Review of positive PBAC recommendations not accepted by applicants - Added
        4. ETANERCEPT (Rymti®) – Review of positive PBAC recommendations not accepted by applicants - Added
        5. ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS (EAA Supplement™) – Review of positive PBAC recommendations not accepted by applicants - Added
        6. INSULIN ASPART (Truvelog; Truvelog Solostar®) – Review of positive PBAC recommendations not accepted by applicants - Added
        7. IXEKIZUMAB (Taltz®) – Review of positive PBAC recommendations not accepted by applicants - Added
        8. MELATONIN (Slenyto®) – Review of positive PBAC recommendations not accepted by applicants - Added
        9. RISANKIZUMAB (Skyriz®) – Review of positive PBAC recommendations not accepted by applicants - Added
        10. SECUKINUMAB (Cosentyx®) – Review of positive PBAC recommendations not accepted by applicants - Added
        11. DAUNORUBICIN AND CYTARABINE (Vyxeos®) – Added
        12. SECUKINUMAB (Cosentyx®) – Added
        13. MAVACAMTEN (Camzyos®) – Added
        14. SACITUZUMAB GOVITECAN (Trodelvy®) – Added
        15. DOSTARLIMAB (Jemperli®) – Purpose of submission amended
        16. VARICELLA ZOSTER VIRUS RECOMBINANT VACCINE (Shingrix®) – Added
        17. APREMILAST (Otezla®) – Drug form amended
        18. DUPILUMAB (Dupixent®) and UPADACITINIB (Rinvoq®) – Added
        19. OMALIZUMAB (Xolair®) – Systematic review to supplement DUSC Analysis – Drug form amended
        20. APREMILAST (Otezla®) – Sub-committee DUSC Analysis – Drug form amended
        21. DUPILIMAB (Dupixent®) - Sub-committee DUSC Analysis – Drug form amended
        22. LISDEXAMFETAMINE (Vyvanse®) - Sub-committee DUSC Analysis – Drug form amended
        23. VENETOCLAX (Venclexta®) - Sub-committee DUSC Analysis – Drug form amended
        24. MIDAZOLAM (Zyamis®) – Added
        25. IMATINIB, DASATINIB, NILOTINIB, PONATINIB, ASCIMINIB (all brands and strengths) – Added
        26. MOLNUPIRAVIR (Lagevrio®) – Added
        27. APREMILAST (Otezla®) – Drug form amended
        28. TISLELIZUMAB (Tevimbra®) – To be considered at a future PBAC meeting
        29. IMATINIB, DASATINIB, NILOTINIB, PONATINIB, ASCIMINIB (All brands and strengths) – To be considered at a future PBAC meeting
        30. DURVALUMAB (Infinzi®) – Review of positive PBAC recommendations not accepted by applicants – Removed – sponsor has advised PBS listing is progressing
        31. ESSENTIAL AMINO ACIDS FORMULA WITH VITAMINS AND MINERALS (EAA Supplement™) – Review of positive PBAC recommendations not accepted by applicants – Removed – sponsor has advised PBS listing is progressing