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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.) |
| --- | --- | --- |
| ABEMACICLIBTablet 50 mgTablet 100 mgTablet 150 mgVerzenio®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. |
| ADALIMUMABInjection 40 mg in 0.4 mL pre-filled syringeInjection 40 mg in 0.4 mL pre-filled penHadlima®ORGANON PHARMA PTY LTD(New listing) | Severe Crohn diseaseModerate to severe ulcerative colitisSevere active juvenile idiopathic arthritis Complex refractory fistulising Crohn diseaseSevere active rheumatoid arthritisSevere psoriatic arthritisAnkylosing spondylitis Severe chronic plaque psoriasisModerate 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. |
| APREMILASTTablet 30 mgPack containing 4 tablets 10 mg, 4 tablets 20 mg and 19 tablets 30 mgOtezla®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 + FORMOTEROLPowder 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 dosesBufomix 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®. |
| CABOZANTINIBTablet 20 mgTablet 40 mgTablet 60 mgCabometyx®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. |
| CEMIPLIMABSolution for I.V. infusion 350 mg in 7 mLLibtayo®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 HYDROCHLORIDEGel 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. |
| CLADRIBINETablet 10 mgMavenclad®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 CYTARABINEPowder for I.V infusion containing daunorubicin 44 mg and cytarabine 100 mgVyxeos®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). |
| DIFELIKEFALINSolution for I.V. injection 50 micrograms in 1 mL vialKorsuva®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. |
| DOSTARLIMABSolution concentrate for I.V. infusion 500 mg in 10 mLJemperli®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. |
| DUPILUMABInjection 200 mg in 1.14 mL single dose pre-filled syringeInjection 300 mg in 2 mL single dose pre-filled syringeDupixent®SANOFI-AVENTIS AUSTRALIA PTY LTDUPADACITINIBTablet 15 mg Tablet 30 mgRinvoq®ABBVIE PTY LTD(Matters outstanding) | Severe atopic dermatitis (AD) | PBAC consideration of the cost-effectiveness of dupilumab and upadacitinib for severe AD. |
| EDARAVONESolution concentrate for injection 30 mg in 20 mLRadicava®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. |
| ELTROMBOPAGTablet 25 mgTablet 50 mgRevolade®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. |
| EMPAGLIFLOZINTablet 10 mgJardiance®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 + SALMETEROLPowder for oral inhalation in breath actuated device containing fluticasone propionate 250 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 dosesPowder 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 ETHYLCapsule 1 gVazkepa®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, ASCIMINIBAll brands and strengthsVarious 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. |
| IVACAFTORSachet containing granules 25 mgSachet containing granules 50 mgSachet containing granules 75 mgTablet 150 mgKalydeco®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. |
| LENACAPAVIRTablet 300 mg Injection set containing 2 vials lenacapavir sodium solution for injection 463.5 mg in 1.5 mL and 2 disposable syringesSunlenca®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. |
| LENALIDOMIDECapsule 20 mgLenalide®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. |
| MARIBAVIRTablet 200 mgLivtencity®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. |
| MAVACAMTENCapsule 2.5 mgCapsule 5 mgCapsule 10 mgCapsule 15 mgCamzyos®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 ACETATESuspension for injection 150 mg in 1 mL pre-filled syringeDepo-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 VACCINEInjection 0.5 mLMenveo®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 |
| MIDAZOLAMOromucosal solution in pre-filled syringe 2.5 mg in 0.25 mLOromucosal solution in pre-filled syringe 5 mg in 0.5 mLOromucosal solution in pre-filled syringe 7.5 mg in 0.75 mLOromucosal solution in pre-filled syringe 10 mg in 1 mLZyamis®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. |
| MOLNUPIRAVIRCapsule 200 mgLagevrio®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 RITONAVIRPack containing 4 tablets nirmatrelvir 150 mg and 2 tablets ritonavir 100 mg, 5Paxlovid®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. |
| NIVOLUMABInjection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mLOpdivo®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. |
| OLAPARIBTablet 100 mgTablet 150 mgLynparza®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. |
| OLAPARIBTablet 100 mgTablet 150 mgLynparza®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. |
| OSIMERTINIBTablet 40 mgTablet 80 mgTagrisso®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. |
| OXYBUTYNINTransdermal 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 mLKeytruda®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 syringePrevenar 20®PFIZER AUSTRALIA PTY LTD(New listing) | Prevention of pneumococcal disease | To request an NIP listing for paediatric populations. |
| RISANKIZUMABInjection 150 mg in 1 mL pre-filled syringeInjection 150 mg in 1 mL pre-filled penSkyrizi®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 GOVITECANPowder for injection 180 mgTrodelvy®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. |
| SECUKINUMABSolution for injection 300 mg in 2 mL pre-filled syringeSolution for injection 150 mg in 1 mL pre-filled syringeSolution for injection 150 mg in 1 mL pre-filled penSolution for injection 300 mg in 2 mL pre-filled penCosentyx®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. |
| SEMAGLUTIDEInjection 0.25 mg in 0.5 mL pre-filled single dose penInjection 0.5 mg in 0.5 mL pre-filled single dose penInjection 1.0 mg in 0.5 mg pre-filled single dose penInjection 1.7 mg in 0.75 mL pre-filled single dose penInjection 2.4 mg in 0.75 mL pre-filled single dose penWegovy®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. |
| TERIPARATIDEInjection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled cartridgeTeriparatide 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®. |
| TERIPARATIDEInjection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled penTerrosa®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. |
| TISLELIZUMABSolution concentrate for injection 100 mg in 10 mLTevimbra®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 DERUXTECANPowder for I.V. infusion 100 mgEnhertu®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 VACCINEInjection 1 vial & adjuvant substance diluent 0.5 mL vialShingrix®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. |
| ADALIMUMABInjection 40 mg in 0.8 mL pre-filled penInjection 40 mg in 0.8 mL pre-filled syringeHulio®Alphapharm Pty Ltd(Review of positive PBAC recommendations not accepted by applicants) | Severe Crohn diseaseUlcerative colitisJuvenile idiopathic arthritisComplex refractory fistulising Crohn diseaseRheumatoid arthritisPsoriatic arthritisAnkylosing spondylitisChronic plaque psoriasisHiradenitis suppurative | - |
| BEVACIZUMABSolution for I.V. infusion 100 mg in 4 mLSolution for I.V. infusion 400 mg in 16 mLZirabev®Pfizer Australia Pty Ltd(Review of positive PBAC recommendations not accepted by applicants) | Metastatic colorectal cancerAdvanced, metastatic or recurrent non-squamous non-small lung cancerRelapsed or recurrent glioblastomaEpithelial ovarian, fallopian tube or primary peritoneal cancerCervical cancer | - |
| ETANERCEPTInjection 50 mg in 1 mL single use pre-filled syringeRymti®Alphapharm Pty Ltd(Review of positive PBAC recommendations not accepted by applicants) | Rheumatoid arthritisPlaque psoriasisAnkylosing spondylitisPsoriatic arthritisJuvenile idiopathic arthritisPaediatric plaque psoriasis | - |
| INSULIN ASPARTInjection (human analogue), cartridge 100 units per mL, 3 mLInjection (human analogue), pre-filled pen, 100 units per mL, 3 mLTruvelog®Truvelog Solostar®Sanofi-Aventis Australia Pty Ltd(Review of positive PBAC recommendations not accepted by applicants) | Diabetes mellitus | - |
| IXEKIZUMABInjection 80 mg in 1 mL single dose pre-filled penTaltz®Eli Lilly Australia Pty Ltd(Review of positive PBAC recommendations not accepted by applicants) | Non-radiographic axial spondyloarthritis | - |
| MELATONINTablet 1 mgTablet 5 mgSlenyto®Aspen Pharmacare Australia Pty Ltd(Review of positive PBAC recommendations not accepted by applicants) | Smith-Magenis syndrome | - |
| RISANKIZUMABInjection 150 mg in 1 mL pre-filled penInjection 150 mg in 1 mL pre-filled syringeSkyrizi®AbbVie Pty Ltd(Review of positive PBAC recommendations not accepted by applicants) | Severe chronic plaque psoriasis | - |
| SECUKINUMABInjection 75 mg in 0.5 mL pre-filled syringeInjection 150 mg in 1 mL pre-filled penInjection 300 mg in 2 mL pre-filled syringeInjection 300 mg in 2 mL pre-filled penCosentyx®Novartis Pharmaceuticals Australia Pty Ltd(Review of positive PBAC recommendations not accepted by applicants | Paediatric psoriasis |  |
| OMALIZUMABInjection 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. |
| APREMILASTTablet 30 mgPack containing 4 tablets 10 mg, 4 tablets 20 mg and 19 tablets 30 mgOtezla®AMGEN AUSTRALIA PTY LIMITED(Sub-committee reportDUSC Analysis) | Severe chronic plaque psoriasis | To assess the utilisation of apremilast for the treatment of severe chronic plaque psoriasis |
| DUPILUMABInjection 200 mg in 1.14 mL single dose pre-filled syringeInjection 300 mg in 2 mL single dose pre-filled syringeDupixent®SANOFI-AVENTIS AUSTRALIA PTY LTD(Sub-committee reportDUSC Analysis) | Chronic severe atopic dermatitis | To assess the utilisation of dupilumab for the treatment of chronic severe atopic dermatitis |
| LISDEXAMFETAMINECapsule containing lisdexamfetamine dimesilate 20 mgCapsule containing lisdexamfetamine dimesilate 30 mgCapsule containing lisdexamfetamine dimesilate 40 mgCapsule containing lisdexamfetamine dimesilate 50 mgCapsule containing lisdexamfetamine dimesilate 60 mgCapsule containing lisdexamfetamine dimesilate 70 mgVyvanse®TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD.(Sub-committee reportDUSC Analysis) | Attention deficit hyperactivity disorder | To assess the utilisation of lisdexamfetamine for the treatment of attention deficit hyperactivity disorder |
| VENETOCLAXPack containing 14 tablets venetoclax 10 mg and 7 tablets venetoclax 50 mg and 7 tablets venetoclax 100 mg and 14 tablets venetoclax 100 mgTablet 100 mgVenclexta®ABBVIE PTY LTD(Sub-committee reportDUSC 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