|  |
| --- |
| 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.) |
| --- | --- | --- |
| ABIRATERONE AND METHYLPREDNISOLONEPack containing 120 tablets abiraterone (as acetate) 125 mg and 60 tablets methylprednisolone 4 mgYonsa Mpred®SUN PHARMA ANZ PTY LTD(Change to existing listing) | Metastatic hormone sensitive prostate cancer | To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of patients with metastatic hormone sensitive prostate cancer. |
| ACALABRUTINIB Tablet 100 mgCalquence®ASTRAZENECA PTY LTD(Change to existing listing) | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) | Resubmission to request a General Schedule Authority Required (Telephone/Online) listing, for use as monotherapy or in combination with obinutuzumab, for the treatment of previously untreated CLL or SLL. |
| ADALIMUMABInjection 40 mg in 0.4 mL pre-filled penInjection 40 mg in 0.4 mL pre-filled syringeInjection 80 mg in 0.8 mL pre-filled syringeArdalicip® CIPLA AUSTRALIA 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 listing of an adalimumab biosimilar under the same conditions as its reference biologic. |
| ATOGEPANTTablet 60 mgAquipta®ALLERGAN AUSTRALIA PTY LIMITED(New listing) | Prophylaxis of migraine  | To request a General Schedule Authority Required (STREAMLINED) listing for the prophylaxis of high frequency episodic and chronic migraine. |
| AVACOPANCapsule 10 mgTavneos®VIFOR PHARMA PTY LIMITED(New listing) | Severe active granulomatosis with polyangiitis (GPA) and severe active microscopic polyangiitis (MPA)  | To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of severe active GPA and severe active MPA in combination with rituximab or cyclophosphamide/azathioprine. |
| BUDESONIDETablet 500 micrograms (orally disintegrating) Tablet 1 mg (orally disintegrating)Jorveza®DR FALK PHARMA AUSTRALIA PTY LTD(Change to existing listing) | Eosinophilic oesophagitis | To request PBAC advice regarding removal of the histological assessment to determine eligibility for continuing treatment. |
| CABOTEGRAVIRSuspension for injection 600 mg in 3 mLApretude®ViiV HEALTHCARE PTY LTD(New listing) | Pre-exposure prophylaxis of HIV infection  | To request a General Schedule Authority Required (STREAMLINED) listing for use as pre-exposure prophylaxis for HIV infection in persons in whom tenofovir/emtricitabine is contraindicated. |
| CALCIPOTRIOL WITH BETAMETHASONEFoam containing calcipotriol 50 micrograms with betamethasone 500 micrograms (as dipropionate) per g, 60 gEnstilar® LEO Pharma Pty Ltd(Change to existing listing) | Chronic stable plaque type psoriasis vulgaris | To request a General Schedule Authority Required (STREAMLINED) listing with an increased maximum quantity of two and maximum repeat of one. |
| DAPAGLIFLOZINTablet 10 mg Forxiga®ASTRAZENECA PTY LTD(Change to existing listing) | Chronic heart failure | To request a General Schedule Authority Required (STREAMLINED) listing for patients with chronic heart failure with preserved ejection fraction (HFpEF). |
| DAPRODUSTATTablet 1 mgTablet 2 mgTablet 4 mgTablet 6 mgTablet 8 mgJesduvroq®GLAXOSMITHKLINE AUSTRALIA PTY LTD(New listing)To be considered at a future PBAC meeting | Anaemia associated with chronic kidney disease | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of anaemia associated with chronic kidney disease. |
| 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 | 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). |
| 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(Other matters) | Chronic severe atopic dermatitis | To request the PBAC consider the previously estimated utilisation for chronic severe atopic dermatitis.  |
| DURVALUMABSolution concentrate for I.V. infusion 120 mg in 2.4 mL vialSolution concentrate for I.V. infusion 500 mg in 10 mL vialImfinzi®ASTRAZENECA PTY LTD(Change to existing listing) | Biliary tract cancer  | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Pharmaceutical Benefits Schedule (PBS) Authority Required (STREAMLINED) listing for the treatment of advanced biliary tract cancer. |
| ENOXAPARINInjection containing enoxaparin sodium 20 mg (2,000 I.U. anti-Xa) in 0.2 mL pre‑filled syringeInjection containing enoxaparin sodium 40 mg (4,000 I.U. anti-Xa) in 0.4 mL pre‑filled syringeInjection containing enoxaparin sodium 60 mg (6,000 I.U. anti-Xa) in 0.6 mL pre‑filled syringeInjection containing enoxaparin sodium 80 mg (8,000 I.U. anti-Xa) in 0.8 mL pre‑filled syringeInjection containing enoxaparin sodium 100 mg (10,000 I.U. anti-Xa) in 1 mL pre‑filled syringeInjection containing enoxaparin sodium 120 mg (12,000 I.U. anti-Xa) in 0.8 mL pre‑filled syringeInjection containing enoxaparin sodium 150 mg (15,000 I.U. anti-Xa) in 1 mL pre‑filled syringeExaraneTMExarane ForteTMJUNO PHARMACEUTICALS PTY LTD(New listing) | Thrombo-embolic disorders | To request listing of an enoxaparin biosimilar under the same conditions as its reference biologic, and to request a General Schedule Restricted Benefit listing for haemodialysis and a General Schedule unrestricted listing of two new forms under the same conditions as the currently listed forms. |
| ESKETAMINE Nasal spray solution 28 mg in 0.2 mLSpravato®JANSSEN-CILAG PTY LTD(New listing) | Treatment resistant depression | Resubmission to request a Section 100 (Highly Specialised Drug Program) Authority Required (Telephone/Online) listing for the treatment of patients with treatment resistant depression. |
| FOSLEVODOPA WITH FOSCARBIDOPASolution for subcutaneous infusion foslevodopa 2400 mg with foscarbidopa 120 mg in 10 mLVyalev®ABBVIE PTY LTD(New listing)To be considered at a future PBAC meeting | Advanced Parkinson's Disease | To request a General Schedule and Section 100 (Highly Specialised Drugs Program) Authority Required (STEAMLINED) listing for the treatment of advanced Parkinson’s disease with severe disabling motor fluctuations not adequately controlled by oral therapy. |
| IXEKIZUMABInjection 80 mg in 1 mL single dose pre-filled penTaltz® ELI LILLY AUSTRALIA PTY LTD(Other matters) | Non-radiographic axial spondyloarthritis (nr-AxSpA) | To request the PBAC consider listing ixekizumab for the treatment of nr-AxSpA in a pack size of two injections. |
| LUMACAFTOR AND IVACAFTORSachet containing granules, lumacaftor 150 mg with ivacaftor 188 mgSachet containing granules, lumacaftor 75 mg with ivacaftor 94 mgSachet containing granules, lumacaftor 100 mg with ivacaftor 125 mgOrkambi®VERTEX PHARMACEUTICALS (AUSTRALIA) PTY. LTD.(Change to existing listing) | Cystic fibrosis | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of cystic fibrosis patients homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene from age 1 to less than 2 years. |
| 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. |
| MIRIKIZUMAB Solution concentrate for I.V. infusion 300 mg in 15 mLSolution for injection 100 mg in 1 mL pre‑filled penOmvoh®ELI LILLY AUSTRALIA PTY LTD(New listing) | Moderate to severe ulcerative colitis (MSUC)  | To request General Schedule and Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listings for the treatment MSUC in patients who have had an inadequate response, lost response, or are intolerant/contraindicated to conventional treatments or biologic/targeted synthetic therapies. |
| MOBOCERTINIBCapsule 40 mgExkivity®TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD.(New listing) | Locally advanced or metastatic non-small cell lung cancer (NSCLC) | Resubmission to request a General Schedule Authority Required (Telephone/Online) listing for the treatment of adults with epidermal growth factor receptor exon 20 insertion positive locally advanced or metastatic (Stage IIIB, IIIC or IV) NSCLC who have received platinum-based chemotherapy. |
| MOLNUPIRAVIRCapsule 200 mgLagevrio®MERCK SHARP & DOHME (AUSTRALIA) PTY LTD(Change to existing listing) | Mild to moderate COVID-19 | To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of high risk patients with mild to moderate COVID-19. |
| NIRAPARIBCapsule 100 mgZejula®GLAXOSMITHKLINE AUSTRALIA PTY LTD(Change to existing listing) | Ovarian cancer | To request a General Schedule Authority Required (telephone/online) listing for the treatment of newly diagnosed, advanced (FIGO Stage III-IV) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer. |
| NIVOLUMABInjection concentrate for I.V. infusion 40 mg in 4 mL vialInjection concentrate for I.V. infusion 100 mg in 10 mL vialOpdivo®BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD(Change to existing listing) | Non-small cell lung cancer | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the neoadjuvant treatment of resectable non-small cell lung cancer (NSCLC). |
| NUSINERSENSolution for injection 12 mg in 5 mLSpinraza®BIOGEN AUSTRALIA PTY LTD(Change to existing listing) | Pre-symptomatic spinal muscular atrophy (SMA)  | Resubmission to request a Section 100 (Highly Specialised Drug Program) Authority Required (Written) listing for treatment of individuals with pre-symptomatic SMA with 3 copies of the survival motor neuron 2 (SMN2) gene, aged less than 18 years. |
| OLAPARIBTablet 100 mgTablet 150 mgLynparza®ASTRAZENECA PTY LTD(Change to existing listing) | Ovarian cancer, fallopian tube and primary peritoneal cancer | Resubmission to request a General Schedule Authority Required listing for use in combination with bevacizumab for maintenance therapy in patients with newly diagnosed homologous recombination deficiency (HRD) positive BRCA wild type advanced epithelial ovarian, fallopian tube or primary peritoneal cancer. |
| OLIPUDASE ALFAPowder for I.V. infusion 20 mg Xenpozyme®SANOFI-AVENTIS AUSTRALIA PTY LTD(New listing) | Acid sphingomyelinase deficiency (ASMD) | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of ASMD. |
| ONASEMNOGENE ABEPARVOVECSolution for injection, customised based on patient weightZolgensma®NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED(Change to existing listing) | Pre-symptomatic spinal muscular atrophy (SMA) | Resubmission to request a Section 100 (Highly Specialised Drug Program) Authority Required (Written) listing for the pre-symptomatic treatment of babies with SMA and 3 copies of the SMN2 gene. |
| PATISIRANSolution concentrate for I.V. infusion 10 mg in 5 mLOnpattro®ALNYLAM AUSTRALIA PTY LTD(New listing) | Hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis)  | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of hATTR amyloidosis in adult patients with stage 1 or stage 2 polyneuropathy. |
| PEMBROLIZUMABSolution concentrate for I.V. infusion 100 mg in 4 mLKeytruda®MERCK SHARP & DOHME (AUSTRALIA) PTY LTD(Change to existing listing) | Breast cancer | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of early stage triple negative breast cancer (eTNBC) in patients who have not received prior systemic therapy. |
| POMALIDOMIDECapsule 1 mgCapsule 2 mgPomolideTMJUNO PHARMACEUTICALS PTY LTD(New listing) | Relapsed/refractory multiple myeloma | To request a Section 100 (Highly Specialised Drugs Program)Authority Required listing for the treatment of multiple myeloma of two new forms under the same conditions as the currently listed forms of pomalidomide. |
| RAVULIZUMABSolution concentrate for I.V. infusion 300 mg in 3 mLSolution concentrate for I.V. infusion 1,100 mg in 11 mLUltomiris®Alexion Pharmaceuticals Australasia Pty Ltd(Change to existing listing) | Atypical haemolytic uraemic syndrome (aHUS) | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of aHUS. |
| RAVULIZUMABSolution concentrate for I.V. infusion300 mg in 3 mLSolution concentrate for I.V. infusion 1,100 mg in 11 mLUltomiris®Alexion Pharmaceuticals Australasia Pty Ltd(Change to existing listing) | Paroxysmal nocturnal haemoglobinuria (PNH) | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for paediatric patients with PNH. |
| RIMEGEPANTTablet 75 mgNurtec ODT®PFIZER AUSTRALIA PTY LTD(New listing) | Acute migraine attacks | To request a General Schedule Authority Required (STREAMLINED) listing for adults with migraine who have not responded adequately to treatment of at least two triptans. |
| 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 | 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) | To request a General Schedule Authority Required (Written) listing for the treatment of HS. |
| SELPERCATINIBCapsule 40 mg Capsule 80 mgRetevmo®ELI LILLY AUSTRALIA PTY LTD(New listing) | Non-small cell lung cancer (NSCLC) | To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of rearranged during transfection (RET) fusion-positive, advanced or metastatic NSCLC, irrespective of line of therapy. |
| SOMAPACITANInjection 5 mg in 1.5 mL pre-filled penInjection 10 mg in 1.5 mL pre-filled penInjection 15 mg in 1.5 mL pre-filled penSogroya®NOVO NORDISK PHARMACEUTICALS PTY. LIMITED(New listing) | Paediatric growth hormone deficiency (GHD) | To request a Section 100 (Growth Hormone Program) Authority Required (Written) listing for the treatment of paediatric patients with GHD. |
| SONIDEGIBCapsule 200 mgOdomzo® SUN PHARMA ANZ PTY LTD(Other matters) | Metastatic or locally advanced basal cell carcinoma (BCC) | To request the PBAC consider the previously estimated utilisation for sonidegib and vismodegib for the treatment of metastatic or locally advanced BCC. |
| TAFAMIDISCapsule 61 mgVyndamax®PFIZER AUSTRALIA PTY LTD(New listing) | Transthyretin amyloid cardiomyopathy | Resubmission to request a General Schedule Authority Required (Written) listing for the treatment of transthyretin amyloid cardiomyopathy. |
| TAGRAXOFUSPSolution concentrate for I.V. infusion 1 mg in 1 mLElzonris®A.MENARINI AUSTRALIA PTY LIMITED(New listing) | Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) | To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Telephone/Online) listing for the treatment of BPDCN. |
| TIRZEPATIDEInjection 2.5 mg in 0.5 mL pre-filled penInjection 5 mg in 0.5 mL pre-filled penInjection 7.5 mg in 0.5 mL pre-filled penInjection 10 mg in 0.5 mL pre-filled penInjection 12.5 mg in 0.5 mL pre-filled penInjection 15 mg per 0.5 mL pre-filled penMounjaro®ELI LILLY AUSTRALIA PTY LTD(New listing)) | Type 2 Diabetes Mellitus (T2D) | To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of adult patients with inadequately controlled T2D as dual therapy in combination with metformin. |
| TRIENTINECapsule containing trientine dihydrochloride 250 mg (equivalent to 166.7 mg trientine)Trientine Dr.Reddy'sDr Reddy's Laboratories (Australia) Pty Ltd(New listing) | Wilson disease | To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of Wilson disease under the same conditions as the currently listed brand.  |
| USTEKINUMAB Solution concentrate for I.V. infusion 130 mg in 26 mLSolution for injection 90 mg in 1 mL pre-filled syringeStelara®JANSSEN-CILAG PTY LTD(Change to existing listing) | Fistulising Crohn disease | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) IV infusion listing, and a General Schedule Authority Required (Written) subcutaneous injection listing, for the treatment of patients with complex refractory fistulising Crohn disease. |
| VARICELLA ZOSTER VIRUS RECOMBINANT VACCINEInjection [1 vial] & adjuvant substance diluent [0.5 mL vial]Shingrix®GLAXOSMITHKLINE AUSTRALIA PTY LTD(New listing) | Prevention of herpes zoster and post-herpetic neuralgia | Resubmission to request a National Immunisation Program listing for the prevention of herpes zoster and post-herpetic neuralgia, for non-Indigenous individuals aged 65 to 69 years and individuals aged 71 years and older.. |
| ADALIMUMABInjection 20 mg in 0.4 mL pre-filled syringeInjection 40 mg in 0.8 mL pre-filled syringeInjection 40 mg in 0.8 mL pre-filled penAbrilada®Pfizer Australia Pty Ltd(Review of positive PBAC recommendations not accepted by applicants) | Crohn disease, Ulcerative colitis, Juvenile idiopathic arthritis, Rheumatoid arthritis, Psoriatic arthritis, Ankylosing spondylitis, Plaque psoriasis, Hidradenitis suppurativa |  |
| ENOXAPARINInjection containing enoxaparin sodium 120 mg (12,000 I.U. anti-Xa) in 0.8 mL pre-filled syringeInjection containing enoxaparin sodium 150 mg (15,000 I.U. anti-Xa) in 1 mL pre-filled syringeClexane Forte®Enoxaparin Winthrop®Clexane Forte Safety Lock®Sanofi-aventis Australia Pty Ltd(Review of positive PBAC recommendations not accepted by applicants) | Antithrombotic agent |  |
| GUSELKUMABSolution for injection 100 mg in 1 mL pen deviceTremfya®Janssen-Cilag Pty Ltd(Review of positive PBAC recommendations not accepted by applicants) | Chronic plaque psoriasis |  |
| HYDROCORTISONECapsule containing granules 0.5 mgCapsule containing granules 1 mgCapsule containing granules 2 mgCapsule containing granules 5 mgAlkindi®Chiesi Australia Pty Ltd(Review of positive PBAC recommendations not accepted by applicants) | Adrenal insufficiency |  |
| INSULIN ASPARTInjections (human analogue), cartridges, 100 units per mL, 3 mLFiasp®Novo Nordisk Pharmaceuticals Pty Ltd(Review of positive PBAC recommendations not accepted by applicants) | Diabetes mellitus |  |
| TRABECTEBINPowder for I.V. infusion 0.25 mgYondelis®Specialised Therapeutics Pharma Pty Ltd(Review of positive PBAC recommendations not accepted by applicants)WITHDRAWN – listing arrangements under consideration  | Leiomyosarcoma |  |
| OLAPARIBTablet 100 mgTablet 150 mgLynparza®ASTRAZENECA PTY LTD(Sub-committee reportDUSC Analysis) | Ovarian, fallopian tube and primary peritoneal cancer | To assess the utilisation of olaparib for treatment of ovarian, fallopian tube and primary peritoneal cancer. |
| OMALIZUMABInjection 150 mg in 1 mL single dose pre-filled syringeXolair®NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED(Sub-committee reportDUSC Analysis) | Chronic spontaneous urticaria (CSU) | To update the June 2020 DUSC predicted versus actual analysis of omalizumab for CSU including additional analyses on the trend in prescribing a higher dose of omalizumab for CSU and the age distribution of PBS patients. |

Version 5

Items added or amended

1. ACALABRUTINIB (Calquence®) – submission purpose amended

Items added or amended previously

1. BUDESONIDE (Jorveza®) – added
2. RAVULIZUMAB (Ultomiris®) – added
3. TRABECTEBIN (Yondelis®) – Review of positive PBAC recommendations not accepted by applicants – withdrawn, listing arrangements [under consideration](https://www.pbs.gov.au/medicinestatus/document/543.html)
4. DAPRODUSTAT (Jesduvroq®) – to be considered at future PBAC meeting
5. OLAPARIB (Lynparza®) – added
6. NIRAPARIB (Zejula®) – added
7. TIRZEPATIDE (Mounjaro®) – forms amended
8. FOSLEVODOPA WITH FOSCARBIDOPA (Vyalev®) - to be considered at a future PBAC meeting
9. DAPRODUSTAT (Jesduvroq®) – brand name corrected
10. CABOTEGRAVIR (Apretude®) – brand name corrected
11. ONASEMNOGENE ABEPARVOVEC (Zolgensma®) – indication amended
12. USTEKINUMAB (Stelara®) – submission type amended
13. MOLNUPIRAVIR (Lagevrio®) – purpose of submission amended
14. DURVALUMAB (Imfinzi®) – added
15. FOSLEVODOPA WITH FOSCARBIDOPA (Vyalev®) – form amended
16. IXEKIZUMAB (Taltz®) – purpose of submission amended
17. NIVOLUMAB (Opdivo®) – added
18. OLIPUDASE ALFA (Xenpozyme®) – form amended & strength removed
19. PEMBROLIZUMAB (Keytruda®) – added
20. VARICELLA ZOSTER VIRUS RECOMBINANT VACCINE (Shingrix®) – added
21. ADALIMUMAB (Abrilada®) – Review of positive PBAC recommendations not accepted by applicants – added
22. CERTOLIZUMAB PEGOL (Cimzia®) – Review of positive PBAC recommendations not accepted by applicants
23. ENOXAPARIN (Clexane Forte®, Enoxaparin Winthrop®, Clexane Forte Safety Lock®) – Review of positive PBAC recommendations not accepted by applicants – added
24. GUSELKUMAB (Tremfya®) – Review of positive PBAC recommendations not accepted by applicants – added
25. HYDROCORTISONE (Alkindi®) – Review of positive PBAC recommendations not accepted by applicants – added
26. INSULIN ASPART (Fiasp®) – Review of positive PBAC recommendations not accepted by applicants – added
27. TRABECTEBIN (Yondelis®) – Review of positive PBAC recommendations not accepted by applicants – added
28. OLAPARIB (Lynparza®) – Sub-committee report DUSC Analysis – added
29. OMALIZUMAB (Xolair®) – Sub-committee report DUSC Analysis – added
30. ACALABRUTINIB (Calquence®) ­– purpose of submission amended