PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
July 2023 PBAC MEETING

Closing date for consumer comments 24 May 2023

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.

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- *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.

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.

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 METHYLPREDNISOLONE Pack containing 120 tablets abiraterone (as acetate) 125 mg and 60 tablets methylprednisolone 4 mg Yonsa 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.

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ACALABRUTINIB Tablet 100 mg Calquence® 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.
ADALIMUMAB Injection 40 mg in 0.4 mL pre-filled pen Injection 40 mg in 0.4 mL pre-filled syringe Injection 80 mg in 0.8 mL pre-filled syringe Ardalicip® 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.
ATOGEPANT Tablet 60 mg Aquipta® 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.

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AVACOPAN Capsule 10 mg Tavneos® 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.
BUDESONIDE Tablet 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.
CABOTEGRAVIR Suspension for injection 600 mg in 3 mL Apretude® 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.

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CALCIPOTRIOL WITH BETAMETHASONE Foam containing calcipotriol 50 micrograms with betamethasone 500 micrograms (as dipropionate) per g, 60 g Enstilar® 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.
DAPAGLIFLOZIN Tablet 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).

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DAPRODUSTAT Tablet 1 mg Tablet 2 mg Tablet 4 mg Tablet 6 mg Tablet 8 mg Jesduvroq® 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 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	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).

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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 (Other matters)	Chronic severe atopic dermatitis	To request the PBAC consider the previously estimated utilisation for chronic severe atopic dermatitis.
DURVALUMAB Solution concentrate for I.V. infusion 120 mg in 2.4 mL vial Solution concentrate for I.V. infusion 500 mg in 10 mL vial Imfinzi® 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.

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ENOXAPARIN Injection containing enoxaparin sodium 20 mg (2,000 I.U. anti-Xa) in 0.2 mL pre-filled syringe Injection containing enoxaparin sodium 40 mg (4,000 I.U. anti-Xa) in 0.4 mL pre-filled syringe Injection containing enoxaparin sodium 60 mg (6,000 I.U. anti-Xa) in 0.6 mL pre-filled syringe Injection containing enoxaparin sodium 80 mg (8,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe Injection containing enoxaparin sodium 100 mg (10,000 I.U. anti-Xa) in 1 mL pre-filled syringe Injection containing enoxaparin sodium 120 mg (12,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe Injection containing enoxaparin sodium 150 mg (15,000 I.U. anti-Xa) in 1 mL pre-filled syringe Exarane™ Exarane Forte™ JUNO 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.

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ESKETAMINE Nasal spray solution 28 mg in 0.2 mL Spravato® 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 FOSCARBIDOPA Solution for subcutaneous infusion foslevodopa 2400 mg with foscarbidopa 120 mg in 10 mL Vyalev® 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.

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IXEKIZUMAB Injection 80 mg in 1 mL single dose pre-filled pen Taltz® 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 IVACAFTOR Sachet containing granules, lumacaftor 150 mg with ivacaftor 188 mg Sachet containing granules, lumacaftor 75 mg with ivacaftor 94 mg Sachet containing granules, lumacaftor 100 mg with ivacaftor 125 mg Orkambi® 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.

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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.
MIRIKIZUMAB Solution concentrate for I.V. infusion 300 mg in 15 mL Solution for injection 100 mg in 1 mL pre-filled pen Omvoh® 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.

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MOBOCERTINIB Capsule 40 mg Exkivity® 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.
MOLNUPIRAVIR Capsule 200 mg Lagevrio® 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.
NIRAPARIB Capsule 100 mg Zejula® 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.

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NIVOLUMAB Injection concentrate for I.V. infusion 40 mg in 4 mL vial Injection concentrate for I.V. infusion 100 mg in 10 mL vial Opdivo® 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).
NUSINERSEN Solution for injection 12 mg in 5 mL Spinraza® 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.

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OLAPARIB Tablet 100 mg Tablet 150 mg Lynparza® 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 ALFA Powder 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 ABEPARVOVEC Solution for injection, customised based on patient weight Zolgensma® 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.

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PATISIRAN Solution concentrate for I.V. infusion 10 mg in 5 mL Onpattro® 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.
PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® 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.

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POMALIDOMIDE Capsule 1 mg Capsule 2 mg Pomolide™ JUNO 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.
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 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.

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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 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.
RIMEGEPANT Tablet 75 mg Nurtec 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 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	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.

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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)	To request a General Schedule Authority Required (Written) listing for the treatment of HS.
SELPERCATINIB Capsule 40 mg Capsule 80 mg Retevmo® 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.

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SOMAPACITAN Injection 5 mg in 1.5 mL pre-filled pen Injection 10 mg in 1.5 mL pre-filled pen Injection 15 mg in 1.5 mL pre-filled pen Sogroya® 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.
SONIDEGIB Capsule 200 mg Odomzo® 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.

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TAFAMIDIS Capsule 61 mg Vyndamax® 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.
TAGRAXOFUSP Solution concentrate for I.V. infusion 1 mg in 1 mL Elzonris® 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.

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TIRZEPATIDE Injection 2.5 mg in 0.5 mL pre-filled pen Injection 5 mg in 0.5 mL pre-filled pen Injection 7.5 mg in 0.5 mL pre-filled pen Injection 10 mg in 0.5 mL pre-filled pen Injection 12.5 mg in 0.5 mL pre-filled pen Injection 15 mg per 0.5 mL pre-filled pen Mounjaro® 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.
TRIENTINE Capsule containing trientine dihydrochloride 250 mg (equivalent to 166.7 mg trientine) Trientine Dr.Reddy's Dr 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.

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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.)
USTEKINUMAB Solution concentrate for I.V. infusion 130 mg in 26 mL Solution for injection 90 mg in 1 mL pre-filled syringe Stelara® 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 VACCINE Injection [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. .

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ADALIMUMAB Injection 20 mg in 0.4 mL pre-filled syringe Injection 40 mg in 0.8 mL pre-filled syringe Injection 40 mg in 0.8 mL pre-filled pen Abrilada® 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	
ENOXAPARIN Injection containing enoxaparin sodium 120 mg (12,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe Injection containing enoxaparin sodium 150 mg (15,000 I.U. anti-Xa) in 1 mL pre-filled syringe Clexane Forte® Enoxaparin Winthrop® Clexane Forte Safety Lock® SANOFI-AVENTIS AUSTRALIA PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Antithrombotic agent	

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
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GUSELKUMAB Solution for injection 100 mg in 1 mL pen device Tremfya® JANSSEN-CILAG PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Chronic plaque psoriasis	
HYDROCORTISONE Capsule containing granules 0.5 mg Capsule containing granules 1 mg Capsule containing granules 2 mg Capsule containing granules 5 mg Alkindi® CHIESI AUSTRALIA PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Adrenal insufficiency	

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INSULIN ASPART Injections (human analogue), cartridges, 100 units per mL, 3 mL Fiasp® NOVO NORDISK PHARMACEUTICALS PTY LTD (Review of positive PBAC recommendations not accepted by applicants)	Diabetes mellitus	
TRABECTEBIN Powder for I.V. infusion 0.25 mg Yondelis® SPECIALISED THERAPEUTICS PHARMA PTY LTD (Review of positive PBAC recommendations not accepted by applicants) WITHDRAWN – listing arrangements under consideration	Leiomyosarcoma	

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OLAPARIB Tablet 100 mg Tablet 150 mg Lynparza® ASTRAZENECA PTY LTD (Sub-committee report DUSC Analysis)	Ovarian, fallopian tube and primary peritoneal cancer	To assess the utilisation of olaparib for treatment of ovarian, fallopian tube and primary peritoneal cancer.
OMALIZUMAB Injection 150 mg in 1 mL single dose pre-filled syringe Xolair® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED (Sub-committee report DUSC 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

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
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3. TRABECTEBIN (Yondelis®) – Review of positive PBAC recommendations not accepted by applicants – withdrawn, listing arrangements under consideration
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