PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
November 2022 PBAC MEETING

Closing date for consumer comments 21st September 2022

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.

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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 (New PBS listing)	Prostate cancer	Resubmission to request a General Schedule Authority Required listing of a composite pack for the treatment of castration-resistant metastatic carcinoma of the prostate.
ACALABRUTINIB Capsule 100 mg Calquence® ASTRAZENECA PTY LTD (Change to PBS listing) To be considered at a future PBAC meeting	Chronic lymphocytic leukaemia or small lymphocytic lymphoma	Resubmission to request a General Schedule Authority Required listing, for use in combination with obinutuzumab, for the treatment of previously untreated chronic lymphocytic leukaemia or small lymphocytic lymphoma in patients who are unsuitable for fludarabine-based chemoimmunotherapy.

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ADALIMUMAB Injection 20 mg in 0.2 mL pre-filled syringe 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 pen Injection 80 mg in 0.8 mL pre-filled syringe UPADACITINIB Tablet 15 mg Humira® Rinvoq® ABBVIE PTY LTD (Change to PBS listing)	Severe active rheumatoid arthritis All adalimumab indications except juvenile idiopathic arthritis	To request that the upadacitinib listing for subsequent continuing treatment of severe active rheumatoid arthritis change from Authority Required (Written) to Authority Required (STREAMLINED). To request that the authority levels for the current Humira listings be aligned with currently listed adalimumab biosimilars.
ALIROCUMAB Injection 75 mg in 1 mL single use pre-filled pen Injection 150 mg in 1 mL single use pre-filled pen Praluent® SANOFI-AVENTIS AUSTRALIA PTY LTD (Change to PBS listing) WITHDRAWN	Hypercholesterolaemia	To request an expansion of the current alirocumab listing to change to the low-density lipoprotein cholesterol criterion from 2.6 mmol/L to 1.8 mmol/L, and to allow general practitioners to initiate treatment in consultation with a specialist physician.

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AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE Oral gel 85 g, 30 (PKU Squeezie) PKU Squeezie® VITAFLO AUSTRALIA PTY LIMITED (Change to PBS listing)	Phenylketonuria	To request that PKU Squeezie with new source of vitamin A continue to be listed on the PBS under existing conditions.
AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS, MEDIUM CHAIN TRIGLYCERIDES, 2'-FUCOSYLLACTOSE AND LACTO-N-NEOTETRAOSE Oral powder 400 g Alfamino® NESTLE AUSTRALIA LTD (New PBS listing)	Cows' milk protein enteropathy Severe cows' milk protein enteropathy with failure to thrive Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae Cows' milk anaphylaxis Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein Severe intestinal malabsorption including short bowel syndrome Eosinophilic oesophagitis	To request General Schedule Authority Required listing under the same conditions as the currently listed Alfamino.

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ASCIMINIB Tablet 20 mg Tablet 40 mg Scemblix® Novartis Pharmaceuticals Australia Pty Limited (New PBS listing)	Chronic myeloid leukaemia	Resubmission to request a General Schedule Authority Required listing for the treatment of patients with Philadelphia chromosome-positive chronic myeloid leukaemia in chronic phase previously treated with two or more tyrosine kinase inhibitors.
AVATROMBOPAG Tablet 20 mg Doptelet® SWEDISH ORPHAN BIOVITRUM PTY LTD (New PBS listing)	Chronic immune (idiopathic) thrombocytopenia purpura	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of severe thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenia purpura who have had an inadequate response or are intolerant to corticosteroids and intravenous immunoglobulin.

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BUDESONIDE WITH GLYCOPYRRONIUM AND FORMOTEROL Pressurised inhalation containing budesonide 160 micrograms with glycopyrronium 7.2 micrograms and formoterol fumarate dihydrate 5 micrograms per dose, 120 doses Breztri Aerosphere® DFP-EvoCap ASTRAZENECA PTY LTD (Change to PBS listing)	Chronic obstructive pulmonary disease	To request General Schedule Authority Required (STREAMLINED) listing for a new inhaler device under the same conditions as the current inhaler device.
DAROLUTAMIDE Tablet 300 mg Nubeqa® BAYER AUSTRALIA LTD (Change to PBS listing)	Prostate cancer	To request a General Schedule Authority Required listing, for use in combination with androgen deprivation therapy and docetaxel, for the treatment of metastatic hormone sensitive prostate cancer.
DEUCRAVACITINIB Tablet 6 mg Sotyktu® BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD (New PBS listing)	Plaque psoriasis	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of severe chronic plaque psoriasis, in patients who have not responded to, or have a contraindication or demonstrated intolerance to methotrexate.

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DOSTARLIMAB Solution concentrate for I.V. infusion 500 mg in 10 mL Jemperli® GLAXOSMITHKLINE AUSTRALIA PTY LTD (New PBS listing)	Endometrial cancer	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of recurrent or advanced mismatch repair deficient endometrial cancer that has progressed on or following prior treatment with a platinum-containing regimen.
DUPILUMAB Injection 300 mg in 2 mL single dose autoinjector Injection 200 mg in 1.14 mL single dose autoinjector Dupixent® SANOFI-AVENTIS AUSTRALIA PTY LTD (Change to PBS listing)	Chronic severe atopic dermatitis Uncontrolled severe asthma	To request a General Schedule Authority Required listing for chronic severe atopic dermatitis and a Section 100 (Highly Specialised Drugs Program) Authority Required listing for uncontrolled severe asthma of two new forms under the same conditions as the currently listed forms of dupilumab.

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ELEXACAFTOR WITH TEZACAFTOR AND WITH IVACAFTOR, AND IVACAFTOR Pack containing 56 tablets elexacaftor 100 mg with tezacaftor 50 mg and with ivacaftor 75 mg and 28 tablets ivacaftor 150 mg Pack containing 56 tablets elexacaftor 50 mg with tezacaftor 25 mg and with ivacaftor 37.5 mg and 28 tablets ivacaftor 75 mg Trikafta® VERTEX PHARMACEUTICALS (AUSTRALIA) PTY. LTD. (New PBS listing)	Cystic fibrosis	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of cystic fibrosis in patients who are aged 6 to 11 years and who have at least one F508del mutation on the cystic fibrosis transmembrane conductance regulator (CFTR) gene.
EMPAGLIFLOZIN Tablet 10 mg Jardiance® BOEHRINGER INGELHEIM PTY LTD (Change to PBS listing)	Chronic heart failure	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of chronic heart failure (NYHA classes II, III or IV) in patients with a left ventricular ejection fraction greater than 40%.

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ENFORTUMAB VEDOTIN Powder for I.V. infusion 20 mg Powder for I.V. infusion 30 mg Padcev® Astellas Pharma Australia Pty Ltd (New PBS listing)	Urothelial cancer	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of patients with locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer who have progressed on or after treatment with a platinum-containing chemotherapy regimen and either a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor.
ETANERCEPT Injection 50 mg in 1 mL single use auto-injector, 4 Nepexto® ALPHAPHARM PTY LTD (New PBS listing)	Rheumatoid arthritis Juvenile idiopathic arthritis Psoriatic arthritis Plaque psoriasis Ankylosing spondylitis	To request General Schedule Authority Required listing of an etanercept biosimilar under the same conditions as its reference biologic.
FREMANEZUMAB Solution for injection 225 mg in 1.5 mL single dose pre-filled syringe Solution for injection 225 mg in 1.5 mL single dose autoinjector Ajovy® TEVA PHARMA AUSTRALIA PTY LTD (Change to PBS listing)	Migraine	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of high frequency episodic migraine in patients who have had an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications.

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GLYCOMACROPEPTIDE FORMULA WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND DOCOSAHEXAENOIC ACID AND LOW IN PHENYLALANINE Oral liquid, 237 mL, 15 (PKU Sphere Liquid) PKU Sphere Liquid VITAFLO AUSTRALIA PTY LIMITED (New PBS listing)	Phenylketonuria	To request a General Schedule Restricted Benefit listing for the dietary management of patients with phenylketonuria.
IBRUTINIB Capsule 140 mg Imbruvica® JANSSEN-CILAG PTY LTD (Change to PBS listing) To be considered at a future PBAC meeting	Chronic lymphocytic leukaemia or small lymphocytic lymphoma	To request a General Schedule Authority Required (Written) listing, for use in combination with venetoclax, for the treatment of previously untreated chronic lymphocytic leukaemia or small lymphocytic lymphoma.

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INFLIXIMAB Solution for injection 120 mg in 1 mL pre-filled pen Solution for injection 120 mg in 1 mL pre-filled syringe Remsima® SC CELLTRION HEALTHCARE AUSTRALIA PTY LTD (Change to PBS listing)	Rheumatoid arthritis	To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for initial treatment of severe active rheumatoid arthritis.
LANREOTIDE Injection 60 mg (as acetate) in single dose pre-filled syringe Injection 90 mg (as acetate) in single dose pre-filled syringe Injection 120 mg (as acetate) in single dose pre-filled syringe Mytolac® AMDIPHARM MERCURY (AUSTRALIA) PTY LIMITED (New PBS listing)	Acromegaly Functional carcinoid tumour Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)	To request Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing of a new pre-filled syringe under the same conditions as the current pre-filled syringe.

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LENACAPAVIR Tablet 300 mg Pack containing 2 injection sets 463.5 mg in 1.5 mL Sunlenca® GILEAD SCIENCES PTY LIMITED (New PBS listing)	Human immunodeficiency virus infection	To request both a Section 100 (Highly Specialised Drugs Program) and Section 100 (Highly Specialised Drugs Program – Community Access) Authority Required (STREAMLINED) listing for the treatment of patients with highly multi-drug resistant human immunodeficiency virus type 1 infection.
MAVACAMTEN Capsule 2.5 mg Capsule 5 mg Capsule 10 mg Capsule 15 mg Camzyos® BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD (New PBS listing)	Hypertrophic cardiomyopathy	To request a General Schedule Authority Required listing for the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy.

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MEPOLIZUMAB Injection 100 mg in 1 mL single dose pre-filled pen Nucala® GLAXOSMITHKLINE AUSTRALIA PTY LTD (Change to PBS listing)	Chronic rhinosinusitis with nasal polyps	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of chronic rhinosinusitis with nasal polyps.
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 (New PBS listing)	Epilepsy	Resubmission to request a General Schedule Authority Required listing for the treatment of generalised convulsive status epilepticus in patients with epilepsy aged over 6 months and a high risk of status epilepticus.

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MOBOCERTINIB Capsule 40 mg Exkivity® TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD. (New PBS listing)	Non-small cell lung cancer	To request a General Schedule Authority Required listing for the treatment of adults with epidermal growth factor receptor exon 20 insertion positive locally advanced or metastatic (Stage IIIB/IV) non-small cell lung cancer who have received platinum-based chemotherapy.
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 PBS listing)	Oesophageal carcinoma or gastroesophageal junction carcinoma	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required listing for the adjuvant treatment of patients with oesophageal carcinoma or gastroesophageal junction carcinoma who have previously received platinum-based chemoradiotherapy and surgery.

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NIVOLUMAB plus IPILIMUMAB NIVOLUMAB: Injection concentrate for I.V. infusion 100 mg in 10 mL, Injection concentrate for I.V. infusion 40 mg in 4 mL IPILIMUMAB: Injection concentrate for I.V. infusion 200 mg in 40 mL, Injection concentrate for I.V. infusion 50 mg in 10 mL Opdivo® Yervoy® BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD (Change to PBS listing)	Melanoma	To request an expansion of the current nivolumab plus ipilimumab listing to allow patients who experience disease recurrence either while receiving or within 6 months of completing adjuvant treatment with an anti-programmed death-1 (PD-1) based therapy to receive nivolumab plus ipilimumab in the metastatic setting.
OLAPARIB Tablet 100 mg Tablet 150 mg Lynparza® AstraZeneca Pty Ltd (Change to PBS listing)	Ovarian 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.

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ONASEMNOGENE ABEPARVOVEC Solution for injection, customised based on patient weight Zolgensma® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED (Change to PBS listing)	Spinal muscular atrophy	To request an expansion of the current onasemnogene abeparvovec listing to include the presymptomatic treatment of children with 3 copies of the SMN2 gene with spinal muscular atrophy.
OZANIMOD Capsule 920 micrograms Pack containing 4 capsules 230 micrograms and 3 capsules 460 micrograms Zeposia® CELGENE PTY LIMITED (Other matters)	Ulcerative colitis	To request the PBAC consider its previous recommendation to list ozanimod for the treatment of moderate to severe ulcerative colitis on a cost-minimisation basis with the least costly alternative disease-modifying anti-rheumatic drug.
PATIROMER Sachet, 8.4 g powder for oral liquid Sachet, 16.8 g powder for oral liquid Veltassa® VIFOR PHARMA PTY LIMITED (New PBS listing)	Hyperkalaemia	Resubmission to request a General Schedule Authority Required listing for the treatment of chronic hyperkalaemia in patients with stage 3 or stage 4 chronic kidney disease.

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PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® MERCK SHARP & DOHME (AUSTRALIA) PTY LTD (Other matters)	Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer	To request the PBAC consider the previously estimated utilisation for locally advanced or metastatic urothelial cancer.
PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® MERCK SHARP & DOHME (AUSTRALIA) PTY LTD (Change to PBS listing)	Cervical cancer	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required listing for the treatment of persistent, recurrent or metastatic (stage IVB) squamous cell carcinoma, adenocarcimoma and adenosquamous carcinoma of the cervix in patients whose tumours express PD-L1 combined positive score equal to or greater than 1.

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PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE, 20-VALENT ADSORBED 0.5 mL pre filled syringe Prevenar 20® PFIZER AUSTRALIA PTY LTD (New NIP listing)	Prevention of pneumococcal disease	To request a National Immunisation Program listing for the prevention of pneumococcal disease.
POLATUZUMAB VEDOTIN Powder for I.V. infusion 30 mg Powder for I.V. infusion 140 mg Polivy® ROCHE PRODUCTS PTY LTD (New PBS listing)	Diffuse large B-Cell lymphoma	To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for use in combination with rituximab, cyclophosphamide, doxorubicin and prednisone, for the treatment of previously untreated diffuse large B-cell lymphoma.

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RANIBIZUMAB Solution for ocular implant 39.5 mg in 0.395 mL Susvimo® ROCHE PRODUCTS PTY LTD (New PBS listing) To be considered at a future PBAC meeting	Neovascular (wet) age-related macular degeneration	To request General Schedule Authority Required listing for the treatment of neovascular (wet) age-related macular degeneration responsive to prior anti-vascular endothelial growth factor (anti-VEGF) treatment.
RISEDRONIC ACID Tablet (enteric coated) containing risedronate sodium 35 mg Actonel® EC THERAMEX AUSTRALIA PTY LTD (Change to PBS listing)	Osteoporosis	To request an expansion of the current risedronate listing to include patients with osteoporosis aged below 70 years of age.
SELINEXOR Tablet 20 mg Xpovio® ANTENGENE (AUS) PTY. LTD. (New PBS listing)	Multiple myeloma	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required listing, for use in combination with bortezomib and dexamethasone, for the treatment of relapsed and/or refractory multiple myeloma.

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SELUMETINIB Capsule 10 mg Capsule 25 mg Koselugo® Alexion Pharmaceuticals Australasia Pty Ltd (New PBS listing)	Neurofibromatosis type 1 (NF1)	To request both a Section 100 (Highly Specialised Drugs Program) and Section 100 (Highly Specialised Drugs Program – Community Access) Authority Required listing for the treatment of symptomatic, inoperable plexiform neurofibroma(s) in paediatric patients with NF1.
SOTORASIB Tablet 120 mg Lumakras® AMGEN AUSTRALIA PTY LIMITED (New PBS listing) WITHDRAWN	Non-small cell lung cancer	Resubmission to request a General Schedule Authority Required listing for the treatment of Kirsten rat sarcoma (KRAS) G12C variant non-squamous or not otherwise specified stage IIIB (locally advanced) or stage IV (metastatic) non-small cell lung cancer in patients who have progressed on prior therapy.
UPADACITINIB Tablet 15 mg Rinvoq® ABBVIE PTY LTD (Change to PBS listing)	Non-radiographic axial spondyloarthritis	To request a General Schedule Authority Required (Written) listing for the treatment of non-radiographic axial spondyloarthritis.

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ENOXAPARIN 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 syringe Injection containing enoxaparin sodium 150 mg (15,000 I.U. anti-Xa) in 1 mL syringe 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 syringe Enoxapro® Apotex Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Prevention of deep vein thrombosis; Haemodialysis	

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FOSNETUPITANT (AS CHLORIDE HYDROCHLORIDE) / PALONOSETRON (AS HYDROCHLORIDE) Powder for Injection containing fosnetupitant 235 mg and palonosetron 250 mg Akynzeo IV® Mundipharma Pty Limited (Review of positive PBAC recommendations not accepted by applicants)	Nausea and vomiting	
FULVESTRANT Injection 250 mg in 5 mL pre-filled syringe Faslodex® AstraZeneca Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Breast cancer	

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DURVALUMAB Solution concentrate for I.V. infusion 120 mg in 2.4 mL; Solution concentrate for I.V. infusion 500 mg in 10 mL Imfinzi® AstraZeneca Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Small cell lung cancer	
IBRUTINIB Tablet 140 mg Tablet 280 mg Tablet 420 mg Tablet 560 mg Imbruvica® Janssen-Cilag Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Chronic lymphocytic leukaemia; Small lymphocytic lymphoma; Mantle cell lymphoma	

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PANCREATIC EXTRACT Capsule (containing enteric coated minimicrospheres) providing not less than 20,000 BP units of lipase activity Creon® Mylan Health Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Pancreatic exocrine insufficiency	
ATEZOLIZUMAB All strengths Tecentriq® ROCHE PRODUCTS PTY LTD (Sub-committee report DUSC Analysis)	Small cell lung cancer	To compare the predicted and actual utilisation of atezolizumab for small cell lung cancer since PBS listing.
Medicines for non-small cell lung cancer All brands and strengths Various sponsors (Sub-committee report DUSC Analysis)	Non-small cell lung cancer	To assess the utilisation of PBS listed medicines for treatment of non-small cell lung cancer.

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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.)
Medicines for melanoma All brands and strengths Various sponsors (Sub-committee report DUSC Analysis)	Melanoma	To assess the utilisation of PBS listed medicines for treatment of melanoma.
Medicines for type 2 diabetes mellitus All brands and strengths Various sponsors (Sub-committee report DUSC Analysis)	Type 2 diabetes mellitus	To assess the utilisation of PBS listed medicines for treatment of type 2 diabetes mellitus

Version 7

Item amended

1. GLYCOMACROPEPTIDE FORMULA WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND DOCOSAHEXAENOIC ACID AND LOW IN PHENYLALANINE (PKU Sphere Liquid) – Drug name amended

Items added or amended previously

1. ADALIMUMAB (Humira®) and UPADACITINIB (Rinvoq®) – Strength and drug use for item amended
2. AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS, MEDIUM CHAIN TRIGLYCERIDES, 2'- FUCOSYLLACTOSE AND LACTO-N-NEOTETRAOSE (Alfamino®) – Trade name for item amended
3. ASCIMINIB (Scemblix®) – added
4. DUPILUMAB (Dupixient®) – Purpose of submission for item amended
5. ENFORTUMAB VEDOTIN (Padcev®) – added
6. MIDAZOLAM (Zyamis®) – added
7. NIVOLUMAB (Opdivo®) – added
8. OLAPARIB (Lynparza®) – added
9. RANIBIZUMAB (Susvimo®) – added
10. ALIROCUMAB (Praluent®) – withdrawn
11. BUDESONIDE WITH GLYCOPYRRONIUM AND FORMOTEROL (Breztri Aerosphere® DFP-EvoCap) – Trade name amended

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12. DUPILUMAB (Dupixent®) – Trade name amended
13. DOSTARLIMAB (Jemperli®) – Listing requested by sponsor amended
14. MAVACAMTEN (Camzyos®) – Strengths for item amended
15. Medicines undergoing review of positive PBAC recommendations not accepted by applicants – added
16. OZANIMOD (Zeposia®) – Purpose of submission for item amended
17. SOTORASIB (Lumakras®) – withdrawn
18. Sub-committee report (DUSC Analysis): medicines for type 2 diabetes mellitus – added
19. GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE (PKU Sphere Liquid) – Trade name amended
20. INFLIXIMAB (Remsima® SC) – Drug form amended
21. RANIBIZUMAB (Susvimo®) – To be considered at a future PBAC meeting
22. ACALABRUTINIB (Calquence®) – To be considered at a future PBAC meeting
23. IBRUTINIB (Imbruvica®) – To be considered at a future PBAC meeting