

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA  
MARCH PBAC MEETING**

**Closing date for consumer comments 10 February 2021**

The PBAC agenda primarily consists of applications relating to the new listing of a drug or vaccine on the PBS or the National Immunisation Program.

The PBAC agenda consists of the following:

- 1 Minutes of Previous Meeting**
- 2 Chairman'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 Medicare Australia or the DVA but require the recording of a streamlined authority code (noted as Authority required (STREAMLINED)).

Submissions are categorised broadly as major or minor:

- *Major*: Submissions to list new medicines on the Schedule of Pharmaceutical Benefits or to make substantial changes to current listings are generally classified as major submissions. Major submissions require presentation of an economic evaluation.
- *Minor*: 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 minor submissions. Minor submissions do not usually require the presentation of an economic evaluation.

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Change to listing (Major submission)	ABEMACICLIB  Tablet 50 mg Tablet 100 mg Tablet 150 mg  Verzenio®  Eli Lilly Australia Pty Ltd	Breast cancer	To request an Authority Required (Telephone/Online) listing for the treatment of hormone receptor positive (HR+) and/or human epidermal growth factor receptor 2 negative (HER2-) inoperable locally advanced or metastatic breast cancer.
New listing (Minor submission)	ACICLOVIR  Eye ointment 30 mg per g, 4.5 g  Xorox®  Clinect Pty Ltd	Herpes simplex keratitis	To request a Restricted Benefit listing for a new brand of aciclovir for the treatment of Herpes simplex keratitis under the same conditions as the currently listed aciclovir eye ointment.
New listing (Minor submission)	AMINO ACID FORMULA WITH FAT, CARBOHYDRATE, VITAMINS, MINERALS, TRACE ELEMENTS AND MEDIUM CHAIN TRIGLYCERIDES  Oral powder 800 g  Essential Care Jr  Cortex Health Pty Ltd	Multiple food allergies and various gastrointestinal disorders and allergic conditions	To request an Authority Required (Telephone) listing for the treatment of a number of different GI intolerance and allergy indications under the same conditions as the currently listed comparator.

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Change to listing (Major submission)	ATEZOLIZUMAB  Solution concentrate for I.V. infusion 840 mg in 14 mL  Tecentriq®  Roche Products Pty Ltd	Breast cancer	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the first-line treatment of metastatic triple negative breast cancer.
Change to listing (Minor submission)	AVELUMAB  Solution concentrate for I.V. infusion 200 mg in 10 mL  Bavencio®  Merck Healthcare Pty Ltd	Renal cell carcinoma (RCC)	Re-submission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing, in combination with axitinib, for the first-line treatment of patients with Stage IV clear cell variant RCC.
Change to listing (Major submission)	AVELUMAB  Solution concentrate for I.V. infusion 200 mg in 10 mL  Bavencio®  Merck Healthcare Pty Ltd	Urothelial carcinoma	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of locally advanced (Stage III) or metastatic (Stage IV) urothelial carcinoma.
Change to listing (Minor submission)	BEVACIZUMAB  Solution for I.V. infusion 100 mg in 4 mL Solution for I.V. infusion 400 mg in 16 mL  MVASI®  Amgen Australia Pty Ltd	Non-small cell lung cancer (NSCLC)	To request changes to the restriction wording for MVASI® for treatment of NSCLC under Section 100 (Efficient Funding of Chemotherapy).

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Change to listing  (Major submission)	BRENTUXIMAB VEDOTIN  Powder for I.V. infusion 50 mg  ADCETRIS®  Takeda Pharmaceuticals Australia Pty Ltd	T-cell lymphoma	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the first-line treatment of CD30 positive peripheral T-cell lymphoma.
New listing  (Major submission)	BROLUCIZUMAB  Solution for injection 19.8 mg in 0.165 mL pre-filled syringe  Beovu®  Novartis Pharmaceuticals Australia Pty Ltd	Wet age-related macular degeneration (AMD)	To request an Authority Required (Written) listing for the treatment of neovascular (wet) aged-related macular degeneration.
New listing  (Major submission)	BUDESONIDE  Tablet (orally disintegrating) 1 mg  Jorveza®  Dr Falk Pharma Australia Pty Ltd	Eosinophilic Oesophagitis (EoE)	To request an Authority Required (STREAMLINED) listing for the treatment of EoE.
New listing  (Major submission)	BUROSUMAB  Injection 10 mg in 1 mL Injection 20 mg in 1 mL Injection 30 mg in 1 mL  Crysvita®  Kyowa Kirin Australia Pty Ltd	X-linked hypophosphataemia	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of x-linked hypophosphataemia.

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Changes to listing (Minor submission)	CABAZITAXEL  Concentrated injection containing cabazitaxel 60 mg in 6 mL  Cabazitaxel Ever Pharma  Interpharma Pty Ltd	Prostate cancer	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for a new brand with a different form for the same conditions as the currently listed cabazitaxel.
New listing (Major submission)	CABOTEGRAVIR/CABOTEGRAVIR AND RILPIVIRINE  Tablet containing cabotegravir 30 mg  Vocabria®  Pack containing 1 injection of cabotegravir 600 mg in 3 mL and 1 injection of rilpivirine 900 mg in 3mL  Cabenuva®  ViiV Healthcare Pty Ltd	Human Immunodeficiency virus (HIV)	To request a Section 100 (Highly Specialised Drugs Program - Community Access) Authority Required (STREAMLINED) listing for the treatment of HIV infection in adults who are virologically suppressed.
New listing (Major submission)	CICLOSPORIN  Eye drops 0.1%, single dose units 0.4 mL  Ikervis®  Seqirus (Australia) Pty Ltd	Dry eye disease in patients with keratitis	To request an Authority Required (STREAMLINED) listing for the treatment of dry eye disease with keratitis.

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New listing  (Major submission)	DAROLUTAMIDE  Tablet 300 mg  Nubeqa®  Bayer Australia Ltd	Prostate cancer	To request an Authority Required (Telephone) listing for the treatment of non-metastatic castration resistant carcinoma of the prostate.
New listing  (Major submission)	DECITABINE AND CEDAZURIDINE  Tablet containing decitabine 35 mg + cedazuridine 100 mg  Inqovi®  Otsuka Australia Pharmaceutical Pty Ltd	Myelodysplastic syndromes (MDS) and chronic myelomonocytic leukaemia (CMML)	To request an Authority Required (non-immediate/delayed - In Writing only/Electronic) listing for the treatment of high risk MDS and CMML.
New listing  (Major submission)	DEUTETRABENAZINE  Tablet 6 mg Tablet 9 mg Tablet 12 mg  Austedo®  Teva Pharma Australia Pty Ltd	Chorea associated with Huntington's disease	To request an Authority Required listing for the treatment of mild, moderate and severe chorea associated with Huntington's disease.

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New listing (Major submission)	ELEXACAFITOR/TEZACAFITOR/ IVACAFITOR  Pack containing 56 tablets of elexacaftor 100 mg with tezacaftor 50 mg and ivacaftor 75 mg and 28 tablets of ivacaftor 150 mg  Trikafta®  Vertex Pharmaceuticals (Australia) Pty Ltd	Cystic fibrosis	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of cystic fibrosis in patients aged 12 years or older who have at least one F508del mutation on the cystic fibrosis transmembrane conductance regulator (CFTR) gene.
Change to listing (Major submission)	ENCORAFENIB  Capsule 50 mg Capsule 75 mg  Braftovi®  Pierre Fabre Australia Pty Ltd	Colorectal cancer	To request an Authority Required (STREAMLINED) listing for the treatment of BRAF V600E-variant metastatic (Stage IV) colorectal cancer.
New listing (Major submission)	ESLICARBAZEPINE  Tablet 800 mg  Zebinix®  Stada Pharmaceuticals Australia Pty Ltd	Epilepsy	To request an Authority Required (STREAMLINED) listing for the treatment of epilepsy in patients aged 16 years or older with partial onset seizures with or without secondary generalisation.

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Change to listing (Minor submission)	EVOLOCUMAB  Injection 420 mg in 3.5 mL single use pre-filled cartridge  Repatha®  Amgen Australia Pty Ltd	Familial heterozygous hypercholesterolaemia; Non-familial hypercholesterolaemia; Familial homozygous hypercholesterolaemia	To request an Authority Required listing for a new form of evolocumab under the same conditions as the already listed evolocumab 420 mg/3.5 mL pre-filled pen.
New listing (Major submission)  WITHDRAWN	FILGOTINIB  Tablet 100 mg Tablet 200 mg  Jyseleca®  Gilead Sciences Pty Ltd	Rheumatoid arthritis	To request an Authority Required (Written) listing for the treatment of severe active rheumatoid arthritis.
New listing (Major submission)	GEMTUZUMAB OZOGAMICIN  Powder for injection 5 mg  Mylotarg®  Pfizer Australia Pty Ltd	Acute myeloid leukaemia (AML)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Telephone/Online) listing for the treatment of de novo CD33-positive AML.

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New Listing (Minor submission)	GLATIRAMER  Injection containing glatiramer acetate 20 mg in 1 mL single dose pre-filled syringe Injection containing glatiramer acetate 40 mg in 1 mL single dose pre-filled syringe  Glatira®  Juno Pharmaceuticals Pty Ltd	Multiple sclerosis	To request an Authority Required (STREAMLINED) listing of a new brand with two different strengths under the same conditions as the currently listed glatiramer pre-filled syringe.
New listing (Minor submission)	GUSELKUMAB  Injection 100 mg in 1 mL single use pre-filled pen  Tremfya®  Janssen-Cilag Pty Ltd	Severe Chronic Plaque Psoriasis (CPP)	To request an Authority Required (Written) listing for a new form for the treatment of severe CPP under the same conditions as the currently listed guselkumab injection syringe.
Change to listing (Minor submission)	HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE  Oral semi-solid, 100 g, 36  K.Yo  Vitaflo Australia Pty Ltd	Dietary management of conditions requiring a ketogenic diet	To request a Restricted Benefit listing of a new brand with a different pack size and formulation.

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Change to listing (Minor submission)	HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE  Oral powder 300 g  KetoCal 3:1 KetoCal 4:1  Nutricia Australia Pty Ltd	Ketogenic Diet	To request approval for changing the nutrient composition for the already listed KetoCal 3:1 and KetoCal 4:1.
Change to listing (Major submission)	LACOSAMIDE  Tablet 50 mg Tablet 100 mg Tablet 150 mg Tablet 200 mg Oral solution 10 mg per mL, 200 mL  Vimpat®  UCB Australia Pty Ltd	Epilepsy	To request an Authority Required (STREAMLINED) listing for the treatment of idiopathic generalised epilepsy with primary generalised tonic-clonic seizures.
New listing (Major submission)	MELATONIN  Tablet 1 mg Tablet 5 mg  Slenyto®  Aspen Pharmacare Australia Pty Ltd	Insomnia	To request an Authority Required (Telephone/Online) listing for the treatment of insomnia in patients between the ages of 2 to 18 with autism spectrum disorder and/or Smith-Magenis syndrome.

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Change to listing (Major submission)	NINTEDANIB  Capsule 100 mg Capsule 150 mg  Ofev®  Boehringer Ingelheim Pty Ltd	Progressive fibrosing interstitial lung disease (PF-ILD)	To request an Authority Required (Written) listing for the treatment of PF-ILD.
New listing (Major submission)	NIRAPARIB  Capsule 100 mg  Zejula®  GlaxoSmithKline Australia Pty Ltd	Ovarian, fallopian tube, or primary peritoneal cancer	To request an Authority Required (Telephone) listing for the treatment of platinum-sensitive, relapsed, high grade serous ovarian, fallopian tube or primary peritoneal cancer.
Change to listing (Minor submission)	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	Non-small cell lung cancer (NSCLC)	Resubmission to address the PBAC's concerns about the incremental effectiveness of nivolumab in patients 75 years or older.

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Change to listing  (Major submission)	NIVOLUMAB with IPILIMUMAB  Nivolumab: Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL  Opdivo®  Ipilimumab: Injection concentrate for I.V. infusion 50 mg in 10 mL  Yervoy®  Bristol-Myers Squibb Australia Pty Ltd	Malignant pleural mesothelioma	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the use of nivolumab in combination with ipilimumab for the treatment of malignant pleural mesothelioma.
New listing  (Minor submission)	OBETICHOLIC ACID  Tablet 5 mg, 10 mg  Ocaliva®  Chiesi Australia Pty Ltd	Primary biliary cholangitis (PBC)	To request an Authority Required (Written) listing for the treatment of PBC.
New listing  (Major submission)	OFATUMUMAB  Injection 20 mg in 0.4 mL single use pre-filled pen  Kesimpta®  Novartis Pharmaceuticals Australia Pty Ltd	Multiple sclerosis (MS)	To request an Authority Required (STREAMLINED) listing for the treatment of MS.

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Change to listing (Major submission)	OLAPARIB  Tablet 100 mg Tablet 150 mg  Lynparza®  AstraZeneca Pty Ltd	Prostate cancer	To request an Authority Required (Telephone/Online) listing for the treatment of metastatic castration resistant carcinoma of the prostate.
Change to listing (Major submission)	PEMBROLIZUMAB  Solution concentrate for I.V. infusion 100 mg in 4 mL  Keytruda®  Merck Sharp & Dohme (Australia) Pty Ltd	Colorectal cancer	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of metastatic (Stage IV) mismatch repair deficient colorectal cancer.
New listing (Major submission)	RIPRETINIB  Tablet 50 mg  Qinlock®  Specialised Therapeutics PM Pty Ltd	Gastrointestinal stromal tumour	To request an Authority Required (Written) listing for the treatment of metastatic or unresectable malignant gastrointestinal stromal tumour.
New listing (Major submission)	RISDIPLAM  Powder for oral solution 0.75 mg per 1 mL, 80 mL  Evrysdi®  Roche Products Pty Ltd	Spinal muscular atrophy	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of spinal muscular atrophy.

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New listing (Major submission)  WITHDRAWN	ROXADUSTAT  Tablet 20 mg Tablet 50 mg Tablet 70 mg Tablet 100 mg  Evrenzo®  AstraZeneca Pty Ltd	Anaemia associated with chronic kidney disease	To request an Authority Required (STREAMLINED) listing for the treatment of anaemia associated with chronic kidney disease.
Change to listing (Major submission)	SEMAGLUTIDE  Solution for injection 2 mg in 1.5 mL pre-filled pen Solution for injection 4 mg in 3 mL pre-filled pen  Ozempic®  Novo Nordisk Pharmaceuticals Pty Ltd	Type 2 diabetes mellitus (T2DM)	To request an Authority Required (STREAMLINED) listing for the treatment of T2DM.
New listing (Major submission)	TAFAMIDIS  Capsule 61 mg  Vyndamax®  Pfizer Australia Pty Ltd	Transthyretin cardiac amyloidosis	To request an Authority Required (Written) listing for the treatment of transthyretin cardiac amyloidosis.

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Change listing (Minor submission)	<p align="center">TEDUGLUTIDE</p> <p align="center">Powder for injection 5 mg with diluent</p> <p align="center">Revestive®</p> <p align="center">Takeda Pharmaceuticals Australia Pty Ltd</p>	<p align="center">Short bowel syndrome (SBS)</p>	<p align="center">To extend the Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing to include paediatric patients with SBS.</p>
Change to listing (Minor submission)	<p align="center">TERIPARATIDE</p> <p align="center">Injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled cartridge</p> <p align="center">Terrosa</p> <p align="center">Gedeon Richter Australia Pty Ltd</p>	<p align="center">Severe established osteoporosis</p>	<p align="center">To request Authority Required (STREAMLINED) listing of teriparatide biosimilar under the same conditions as its reference biologic.</p>
Change to listing (Minor submission)	<p align="center">TESTOSTERONE</p> <p align="center">Transdermal cream 50 mg per mL, 50 mL</p> <p align="center">AndroForte® 5</p> <p align="center">Lawley Pharmaceuticals Pty Ltd</p>	<p align="center">Testosterone deficiency</p>	<p align="center">To request a change in the number of repeats for the currently listed testosterone cream.</p>
Change to listing (Minor submission)	<p align="center">TETRACOSACTIDE</p> <p align="center">Compound depot injection 1 mg in 1 mL</p> <p align="center">Synacthen® Depot 1 mg/1 mL</p> <p align="center">Clinect Pty Ltd</p>	<p align="center">Hypsarrhythmia and/or infantile spasms</p>	<p align="center">To request a change in restriction level from Restricted Benefit to Unrestricted Benefit listing.</p>

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New listing (Major submission)	TUCATINIB  Tablet 150 mg Tablet 50 mg  Tukysa®  Lucid Health Consulting Pty Ltd	Breast cancer	To request an Authority Required (Telephone) listing for the treatment of metastatic (Stage IV) human epidermal growth factor receptor 2 (HER2) positive breast cancer.
Change to listing (Major submission)	UPADACITINIB  Tablet 15 mg  Rinvoq®  Abbvie Pty Ltd	Ankylosing spondylitis	To request an Authority Required (Written) listing for the treatment of ankylosing spondylitis.
Change to listing (Major submission)	UPADACITINIB  Tablet 15 mg  Rinvoq®  Abbvie Pty Ltd	Psoriatic arthritis	To request an Authority Required (Written) listing for the treatment of severe psoriatic arthritis.
Change to listing (Major submission)	USTEKINUMAB  Injection 45 mg in 0.5 mL  Stelara®  Janssen-Cilag Pty Ltd	Plaque psoriasis	To request an Authority Required (Written) listing for the treatment of paediatric patients with severe chronic plaque psoriasis.

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Change to listing  (Major submission)	VENETOCLAX  Tablet 100 mg  Venclexta®  Abbvie Pty Ltd	Acute myeloid leukaemia (AML)	To request an Authority Required (Telephone/Online) listing for the treatment of AML.
Subcommittee report (DUSC Analysis)	Nusinersen  Spinraza®  Biogen Australia Pty Ltd	Spinal muscular atrophy (SMA)	To compare the predicted and actual utilisation of nusinersen for the treatment of SMA since PBS listing.
Subcommittee report (DUSC Analysis)	Ocular lubricants  All brands and strengths  Various sponsors	Severe dry eye syndrome	To assess the utilisation of PBS listed ocular lubricants for severe dry eye syndrome.