

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 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 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 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.

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

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.)
ABEMACICLIB Tablet 50 mg Tablet 100 mg Tablet 150 mg Verzenio™ Eli Lilly Australia Pty Ltd (Change to listing)	Breast cancer	To request a General Schedule Authority Required (Written) listing, in combination with adjuvant endocrine therapy, for the treatment of patients with hormone receptor positive (HR+) and human epidermal growth factor receptor 2 negative (HER2-), lymph node-positive, invasive, resected early breast cancer and whose cancer is at high risk of disease recurrence.
ABIRATERONE with METHYPREDNISOLONE 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)	Castration resistant metastatic carcinoma of the prostate	To request a General Schedule Authority Required (STREAMLINED) listing of a composite pack for the treatment of castration resistant metastatic carcinoma of the prostate.

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

<p>Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p>Drug Type and Use (What is the drug used to treat?)</p>	<p>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.)</p>
<p align="center">APREMILAST</p> <p align="center">Tablet 30 mg Pack containing 4 tablets 10 mg, 4 tablets 20 mg and 19 tablets 30 mg</p> <p align="center">Otezla®</p> <p align="center">Amgen Australia Pty Limited</p> <p align="center">(Change to PBS listing)</p>	<p align="center">Severe chronic plaque psoriasis</p>	<p align="center">To request changing the treatment criteria to allow accredited dermatology registrars to initiate treatment in consultation with a dermatologist; and to allow general practitioners to prescribe maintenance treatment.</p>
<p align="center">BECLOMETASONE WITH FORMETEROL</p> <p align="center">Pressurised inhalation containing beclometasone dipropionate 100 micrograms and formoterol fumarate dihydrate 6 micrograms per dose, 120 dose</p> <p align="center">Fostair®</p> <p align="center">Chiesi Australia Pty Ltd</p> <p align="center">(Change to PBS listing)</p>	<p align="center">Chronic obstructive pulmonary disease</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing for the symptomatic treatment of adults with severe chronic obstructive pulmonary disease (FEV1 <50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

<p align="center">Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p align="center">Drug Type and Use (What is the drug used to treat?)</p>	<p align="center">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.)</p>
<p align="center">BECLOMETASONE WITH FORMOTEROL AND GLYCOPYRRONIUM</p> <p>Pressurised inhalation containing beclometasone dipropionate 100 micrograms with formoterol fumarate dihydrate 6 micrograms and glycopyrronium 10 micrograms (as bromide) per dose, 120 doses</p> <p>Pressurised inhalation containing beclometasone dipropionate 200 micrograms with formoterol fumarate dihydrate 6 micrograms and glycopyrronium 10 micrograms (as bromide) per dose, 120 doses</p> <p align="center">Trimbow®</p> <p align="center">Chiesi Australia Pty Ltd</p> <p align="center">(New PBS listing)</p>	<p align="center">Asthma</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing for the maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta2-agonist and an inhaled corticosteroid who experienced one or more asthma exacerbations in the previous year.</p>
<p align="center">BEVACIZUMAB</p> <p>Solution for I.V. infusion 100 mg in 4 mL Solution for I.V. infusion 400 mg in 16 mL</p> <p align="center">Bevaciptin®</p> <p align="center">Cipla Australia Pty Ltd</p> <p align="center">(New PBS listing)</p>	<p align="center">Cancers</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy Program) Unrestricted Benefit listing of bevacizumab biosimilar under the same conditions as the PBS-listed bevacizumab biosimilar.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

<p>Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p>Drug Type and Use (What is the drug used to treat?)</p>	<p>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.)</p>
<p align="center">BIMEKIZUMAB</p> <p>Solution for injection 160 mg in 1 mL pre-filled pen Solution for injection 160 mg in 1 mL pre-filled syringe</p> <p align="center">Bimzelx®</p> <p align="center">UCB Australia Proprietary Limited</p> <p align="center">(New PBS listing)</p>	<p align="center">Plaque psoriasis</p>	<p align="center">To request a General Schedule Authority Required (Written) listing for the treatment of adults with severe plaque psoriasis.</p>
<p align="center">BORTEZOMIB</p> <p>Solution for injection 2.5 mg Solution for injection 3.5 mg</p> <p align="center">Bortezomib Ever Pharma®</p> <p align="center">Interpharma Pty Ltd</p> <p align="center">(New PBS listing)</p>	<p align="center">Multiple Myeloma</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy Program) listing of a new form under the same conditions as the currently listed brands of bortezomib.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

<p>Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p>Drug Type and Use (What is the drug used to treat?)</p>	<p>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.)</p>
<p align="center">BUROSUMAB</p> <p align="center">Injection 10 mg in 1 mL Injection 20 mg in 1 mL Injection 30 mg in 1 mL</p> <p align="center">Crysvita®</p> <p align="center">Kyowa Kirin Australia Pty Ltd</p> <p align="center">(New PBS listing)</p>	<p align="center">X-linked hypophosphataemia</p>	<p align="center">Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of X-linked hypophosphataemia.</p>
<p align="center">CABAZITAXEL</p> <p align="center">Solution concentrate for I.V. infusion 60 mg in 3 mL</p> <p align="center">Cabazitaxel Accord®</p> <p align="center">Accord Healthcare Pty. Ltd.</p> <p align="center">(New PBS listing)</p>	<p align="center">Prostate cancer</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy Program) listing of a new form under the same conditions as the currently listed brands of cabazitaxel.</p>
<p align="center">CANNABIDIOL</p> <p align="center">Oral liquid 100 mg per mL, 100 mL</p> <p align="center">Epidyolex®</p> <p align="center">Chiesi Australia Pty Ltd</p> <p align="center">(Change to PBS listing)</p>	<p align="center">Lennox-Gastaut syndrome</p>	<p align="center">To request that the PBAC reconsider a General Schedule Authority Required listing for the adjunctive treatment of seizures in patients with Lennox-Gastaut syndrome aged 2 years and older.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

<p>Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p>Drug Type and Use (What is the drug used to treat?)</p>	<p>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.)</p>
<p align="center">CARFILZOMIB</p> <p>Powder for injection 10 mg Powder for injection 30 mg Powder for injection 60 mg</p> <p align="center">Kyprolis®</p> <p align="center">Amgen Australia Pty Limited</p> <p align="center">(Change to PBS listing)</p>	<p align="center">Multiple myeloma</p>	<p align="center">Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing, for use in combination with lenalidomide and dexamethasone, for the treatment of relapsed refractory multiple myeloma.</p>
<p align="center">CEMIPLIMAB</p> <p>Solution for I.V. infusion 350 mg in 7 mL</p> <p align="center">Libtayo®</p> <p align="center">Sanofi-aventis Australia Pty Ltd</p> <p align="center">(New PBS listing)</p>	<p align="center">Squamous cell carcinoma</p>	<p align="center">Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of metastatic or locally advanced cutaneous squamous cell carcinoma, in patients who are not candidates for curative surgery or curative radiation.</p>
<p align="center">CICLOSPORIN</p> <p>Eye drops 900 micrograms per mL, single dose units, 0.25 mL, 60</p> <p align="center">Cequa®</p> <p align="center">Sun Pharma ANZ Pty Ltd</p> <p align="center">(New PBS listing)</p>	<p align="center">Chronic severe dry eye disease with keratitis</p>	<p align="center">To request a General Schedule Authority Required listing for the treatment of chronic severe dry eye disease with keratitis under the same restrictions as the currently listed ciclosporin eye drops.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

<p>Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p>Drug Type and Use (What is the drug used to treat?)</p>	<p>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.)</p>
<p>DIPHTHERIA, TETANUS, PERTUSSIS, HEPATITIS B, POLIOMYELITIS AND HAEMOPHILUS INFLUENZAE TYPE B CONJUGATE VACCINE (DTaP-HB-IPV-Hib)</p> <p>0.5 mL pre-filled syringe</p> <p>Vaxelis®</p> <p>sanofi-aventis Australia Pty Ltd</p> <p>(New listing)</p>	<p>Diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and Haemophilus influenzae type b</p>	<p>To request National Immunisation Program listing for the prevention of diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and Haemophilus influenzae type b.</p>
<p>DIROXIMEL FUMARATE</p> <p>Capsule 231 mg</p> <p>Vumerity®</p> <p>Biogen Australia Pty Ltd</p> <p>(New PBS listing)</p>	<p>Multiple sclerosis</p>	<p>To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of relapsing-remitting multiple sclerosis.</p>
<p>DORZOLAMIDE WITH TIMOLOL</p> <p>Eye drops containing dorzolamide 20 mg (as hydrochloride) with timolol 5 mg (as maleate) per mL, 5 mL</p> <p>Vizo-PF Dorzolamim®</p> <p>Aft Pharmaceuticals (Au) Pty Ltd</p> <p>(New PBS listing)</p>	<p>Elevated intra-ocular pressure</p>	<p>To request a General Schedule Restricted Benefit listing of a new form in a preservative-free multi-dose bottle under the same conditions as the currently listed brands of dorzolamide with timolol.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

<p align="center">Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p align="center">Drug Type and Use (What is the drug used to treat?)</p>	<p align="center">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.)</p>
<p align="center">DOSTARLIMAB</p> <p>Solution concentrate for I.V. infusion 500 mg in 10 mL</p> <p align="center">Jemperli®</p> <p align="center">GlaxoSmithKline Australia Pty Ltd</p> <p align="center">(New PBS listing)</p>	<p align="center">Endometrial cancer</p>	<p align="center">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.</p>
<p align="center">DULAGLUTIDE</p> <p>Injection 3 mg in 0.5 mL single dose pre-filled pen</p> <p>Injection 4.5 mg in 0.5 mL single dose pre-filled pen</p> <p align="center">Trulicity®</p> <p align="center">Eli Lilly Australia Pty Ltd</p> <p align="center">(New PBS listing)</p>	<p align="center">Type 2 diabetes mellitus</p>	<p align="center">To request General Schedule Authority Required (STREAMLINED) listings of two new forms for the treatment of patients with Type 2 diabetes mellitus who require treatment intensification to achieve glycaemic targets, as dual therapy in combination with metformin.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

<p align="center">Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p align="center">Drug Type and Use (What is the drug used to treat?)</p>	<p align="center">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.)</p>
<p align="center">DUPILUMAB</p> <p>Injection 200 mg in 1.14 mL single dose pre-filled syringe Injection 300 mg in 2 mL single dose pre-filled syringe</p> <p align="center">Dupixent®</p> <p align="center">sanofi-aventis Australia Pty Ltd</p> <p align="center">(Change to PBS listing)</p>	<p align="center">Atopic dermatitis</p>	<p align="center">To request a General Schedule Authority Required listing for the treatment of severe atopic dermatitis in patients aged 6 to 11 years.</p>
<p align="center">DURVALUMAB</p> <p>Solution concentrate for I.V. infusion 500 mg in 10 mL</p> <p align="center">Imfinzi®</p> <p align="center">AstraZeneca Pty Ltd</p> <p align="center">(Change to PBS listing)</p>	<p align="center">Unresectable Stage III, non-small cell lung cancer</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing of a new maximum amount of 1500 mg with four repeats to allow an additional dosing regimen of durvalumab to allow a fixed-dose 1500 mg every 4 weeks.</p>
<p align="center">ENFORTUMAB VEDOTIN</p> <p>Powder for I.V. infusion 20 mg Powder for I.V. infusion 30 mg</p> <p align="center">Padcev®</p> <p align="center">Astellas Pharma Australia Pty Ltd</p> <p align="center">(New PBS listing)</p>	<p align="center">Urothelial cancer</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer in patients with a WHO performance status of 0 or 1 and 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.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

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.)
ENZALUTAMIDE Capsule 40 mg Xtandi® Astellas Pharma Australia Pty Ltd (Change to PBS listing)	Prostate cancer	To request a General Schedule Authority Required listing, in combination with ongoing androgen-deprivation therapy, for the treatment of non-metastatic castration-resistant prostate cancer.
FREMANEZUMAB Solution for injection 225 mg in 1.5 mL single dose auto-injector Ajovy® Teva Pharma Australia Pty Ltd (New PBS listing)	Chronic migraine	To request General Schedule Authority Required (STREAMLINED) listing of a new form under the same conditions as the PBS-listed fremanezumab pre-filled syringes.
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 auto-injector Ajovy® Teva Pharma Australia Pty Ltd (Change to PBS listing)	Chronic migraine	To request General Schedule Authority Required (STREAMLINED) listing with maximum quantity of three and one repeat to allow quarterly dosing in addition to the existing monthly dosing.

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

<p>Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p>Drug Type and Use (What is the drug used to treat?)</p>	<p>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.)</p>
<p>GALCANEZUMAB Injection 120 mg in 1 mL pre-filled pen Emgality® Eli Lilly Australia Pty Ltd (Change to PBS listing)</p>	<p>Migraine</p>	<p>Resubmission to extend the current General Schedule Authority Required (STREAMLINED) listing to include treatment-resistant high frequency episodic migraine.</p>
<p>GLATIRAMER Injection containing glatiramer acetate 40 mg in 1 mL single dose pre-filled pen Copaxone® Teva Pharma Australia Pty Ltd (New PBS listing)</p>	<p>Multiple sclerosis</p>	<p>To request a General Schedule Authority Required (STREAMLINED) listing of a new form under the same conditions as the PBS-listed glatiramer pre-filled syringe.</p>
<p>GLYCOMACROPEPTIDE FORMULA WITH AMINO ACIDS, CARBOHYDRATES, MINERALS AND LOW PHENYLALANINE Sachets containing oral powder 12.5 g, 30 (PKU GMPPro Mix-In) PKU GMPPro MIX-IN® Nutricia Australia Pty Limited (New PBS listing)</p>	<p>Phenylketonuria</p>	<p>To request a General Schedule Restricted Benefit listing for treatment of phenylketonuria in patients older than 3 years of age.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

<p>Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p>Drug Type and Use (What is the drug used to treat?)</p>	<p>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.)</p>
<p>GLYCOMACROPEPTIDE FORMULA WITH AMINO ACIDS, VITAMINS, MINERALS, TRACE ELEMENTS, CARBOHYDRATE, FAT AND LOW PHENYLALANINE</p> <p>Sachets containing oral powder 33.4 g, 30(PKU GMP^{ro} ULTRA)</p> <p>PKU GMP^{ro} ULTRA®</p> <p>Nutricia Australia Pty Limited</p> <p>(New PBS listing)</p>	<p>Phenylketonuria</p>	<p>To request a General Schedule Restricted Benefit listing for treatment of phenylketonuria in patients older than 3 years of age.</p>
<p>INFLIXIMAB</p> <p>Solution for injection 120 mg in 1 mL pre-filled pen</p> <p>Solution for injection 120 mg in 1 mL pre-filled syringe</p> <p>Remsima® SC</p> <p>Celltrion Healthcare Australia Pty Ltd</p> <p>(New PBS listing)</p>	<p>Ankylosing spondylitis Psoriatic arthritis Chronic plaque psoriasis Refractory fistulising Crohn Disease</p>	<p>To request a General Schedule Authority Required listing for the treatment of ankylosing spondylitis, psoriatic arthritis, chronic plaque psoriasis and refractory fistulising Crohn Disease.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

<p align="center">Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p align="center">Drug Type and Use (What is the drug used to treat?)</p>	<p align="center">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.)</p>
<p align="center">IXAZOMIB</p> <p align="center">Capsule 2.3 mg Capsule 3 mg Capsule 4 mg</p> <p align="center">Ninlaro®</p> <p>Takeda Pharmaceuticals Australia Pty. Ltd.</p> <p align="center">(New PBS listing)</p>	<p align="center">Multiple myeloma</p>	<p align="center">Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required listing, in combination with lenalidomide and dexamethasone, for the treatment of relapsed and/or refractory multiple myeloma in patients who have received at least two prior therapies.</p>
<p align="center">METHYLPHENIDATE</p> <p>Capsule containing methylphenidate hydrochloride 10 mg (modified release) Capsule containing methylphenidate hydrochloride 20 mg (modified release) Capsule containing methylphenidate hydrochloride 30 mg (modified release) Capsule containing methylphenidate hydrochloride 40 mg (modified release) Capsule containing methylphenidate hydrochloride 60 mg (modified release)</p> <p align="center">Ritalin® LA</p> <p>Novartis Pharmaceuticals Australia Pty Limited</p> <p align="center">(Change to PBS listing)</p>	<p align="center">Attention deficit hyperactivity disorder</p>	<p align="center">To request a General Schedule Authority Required listing for the treatment of adult patients with attention deficit hyperactivity disorder under the same population criteria as the currently listed lisdexamfetamine for adult population.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

<p>Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p>Drug Type and Use (What is the drug used to treat?)</p>	<p>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.)</p>
<p align="center">NIRAPARIB Capsule 100 mg Zejula® GlaxoSmithKline Australia Pty Ltd (New PBS listing)</p>	<p align="center">High grade epithelial ovarian, fallopian tube, or primary peritoneal cancer</p>	<p align="center">Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of newly diagnosed, advanced, high grade epithelial ovarian, fallopian tube, or primary peritoneal cancer that is responsive (complete/partial) to platinum-based chemotherapy.</p>
<p align="center">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)</p>	<p align="center">Second-line squamous cell oesophageal carcinoma</p>	<p align="center">To request the PBAC to reconsider its July 2021 recommendation for a Section 100 (Efficient Funding of Chemotherapy Program), Authority Required (STREAMLINED) listing for second-line squamous cell oesophageal carcinoma that have failed treatment with a fluoropyrimidine and platinum containing treatment regimen.</p>
<p align="center">NUSINERSEN Solution for injection 12 mg in 5 mL Spinraza® Biogen Australia Pty Ltd (Change to PBS listing)</p>	<p align="center">Spinal muscular atrophy</p>	<p align="center">Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of adults diagnosed with 5q spinal muscular atrophy with symptom onset prior to 19 years of age (≤18 years of age).</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

<p>Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p>Drug Type and Use (What is the drug used to treat?)</p>	<p>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.)</p>
<p align="center">OZANIMOD</p> <p align="center">Capsule 920 micrograms Pack containing 4 capsules 230 micrograms and 3 capsules 460 micrograms</p> <p align="center">Zeposia®</p> <p align="center">Celgene Pty Limited</p> <p align="center">(Change to PBS listing)</p>	<p align="center">Ulcerative colitis</p>	<p align="center">To request a General Schedule Authority Required (Written) listing for the treatment of moderate to severe ulcerative colitis.</p>
<p align="center">PALBOCICLIB</p> <p align="center">Tablet 75 mg Tablet 100 mg Tablet 125 mg</p> <p align="center">Ibrance®</p> <p align="center">Pfizer Australia Pty Ltd</p> <p align="center">(Change to recommended PBS listing)</p>	<p align="center">Breast cancer</p>	<p align="center">To request a General Schedule Authority Required listing, for use in combination with fulvestrant, for the treatment of hormone receptor positive (HR+) and human epidermal growth factor receptor 2 negative (HER2-) locally advanced inoperable or metastatic breast cancer in patients who have received prior endocrine therapy.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

<p align="center">Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p align="center">Drug Type and Use (What is the drug used to treat?)</p>	<p align="center">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.)</p>
<p align="center">PALIPERIDONE</p> <p>I.M. injection (modified release) 700 mg (as palmitate) in pre-filled syringe I.M. injection (modified release) 1000 mg (as palmitate) in pre-filled syringe</p> <p align="center">Invega Hafyera®</p> <p align="center">Janssen-Cilag Pty Ltd</p> <p align="center">(New PBS listing)</p>	<p align="center">Schizophrenia</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing for the maintenance treatment of schizophrenia in patients who either have been stabilised on PBS-subsidised paliperidone three-monthly injection for at least one injection cycle or PBS-subsidised paliperidone once-monthly for at least four consecutive months.</p>
<p align="center">PEGCETACOPLAN</p> <p>Solution for subcutaneous infusion 1,080 mg in 20 mL</p> <p align="center">Empaveli™</p> <p align="center">Swedish Orphan Biovitrum Pty Ltd</p> <p align="center">(New PBS listing)</p>	<p align="center">Paroxysmal nocturnal haemoglobinuria</p>	<p align="center">To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of adults with paroxysmal nocturnal haemoglobinuria who have an inadequate clinical response to complement component 5 (C5) inhibitor treatment.</p>
<p align="center">PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p align="center">Keytruda®</p> <p align="center">Merck Sharp & Dohme (Australia) Pty Ltd</p> <p align="center">(Change to PBS listing)</p>	<p align="center">Renal cell carcinoma</p>	<p align="center">To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing, in combination with lenvatinib, for the first-line treatment of patients with advanced clear cell variant renal cell carcinoma.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

<p align="center">Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p align="center">Drug Type and Use (What is the drug used to treat?)</p>	<p align="center">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.)</p>
<p align="center">PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p align="center">Keytruda®</p> <p>Merck Sharp & Dohme (Australia) Pty Ltd</p> <p align="center">(Change to PBS listing)</p>	<p align="center">Endometrial cancer</p>	<p>To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required listing, in combination with lenvatinib, for the treatment of patients with advanced endometrial cancer (regardless of biomarker status) who have disease progression following prior systemic therapy. The submission also requests a listing for pembrolizumab monotherapy for those patients with deficient DNA mismatch repair.</p>
<p>QUADRIVALENT INFLUENZA VACCINE (SURFACE ANTIGEN, INACTIVATED, CELL-BASED)</p> <p>Injection 15 microgram in 0.5 mL needle-free pre-filled syringe Injection 15 microgram in 0.5 mL pre-filled syringe with attached needle</p> <p align="center">Flucelvax® Quad</p> <p align="center">Seqirus (Australia) Pty Ltd</p> <p align="center">(New listing)</p> <p align="center">WITHDRAWN</p>	<p align="center">Prevention of influenza</p>	<p>To request National Immunisation Program listing for the prevention of influenza.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

<p>Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p>Drug Type and Use (What is the drug used to treat?)</p>	<p>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.)</p>
<p align="center">RABEPRAZOLE</p> <p>Tablet containing rabeprazole sodium 20 mg (enteric coated)</p> <p align="center">Pariet®</p> <p align="center">Janssen-Cilag Pty Ltd</p> <p align="center">(Change to PBS listing)</p>	<p align="center">Complex gastro-oesophageal reflux disease Scleroderma oesophagus Gastro-oesophageal reflux disease Peptic ulcer</p>	<p>To request a General Schedule Authority Required (STREAMLINED) listing of a new pack size (28 tablets per pack) under the same conditions as the currently listed 20 mg rabeprazole tablets (30 tablets per pack).</p>
<p align="center">RANIBIZUMAB</p> <p>Solution for ocular implant 39.5 mg in 0.395 mL</p> <p align="center">Susvimo®</p> <p align="center">Roche Products Pty Ltd</p> <p align="center">(New PBS listing)</p>	<p align="center">Neovascular (wet) age-related macular degeneration</p>	<p>To request a 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.</p>
<p align="center">RISANKIZUMAB</p> <p>Injection 150 mg in 1 mL pre-filled pen Injection 150 mg in 1 mL pre-filled syringe Injection 75 mg in 0.83 mL pre-filled syringe</p> <p align="center">Skyrizi®</p> <p align="center">AbbVie Pty Ltd</p> <p align="center">(Change to PBS listing)</p>	<p align="center">Severe chronic plaque psoriasis</p>	<p>To request adding a grandfathering restriction to allow eligible patients enrolled in the risankizumab open-label extension trial (M15-997) to transition to PBS-subsidised risankizumab.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

<p>Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p>Drug Type and Use (What is the drug used to treat?)</p>	<p>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.)</p>
<p align="center">RISANKIZUMAB</p> <p>Injection 150 mg in 1 mL pre-filled syringe Injection 150 mg in 1 mL pre-filled pen</p> <p align="center">Skyrizi®</p> <p align="center">AbbVie Pty Ltd</p> <p align="center">(New PBS listing)</p>	<p align="center">Psoriatic arthritis</p>	<p align="center">To request a General Schedule Authority Required (Written) listing for the treatment of severe psoriatic arthritis.</p>
<p align="center">SEBELIPASE ALFA</p> <p>Solution concentrate for I.V. infusion 20 mg in 10 mL</p> <p align="center">Kanuma®</p> <p>Alexion Pharmaceuticals Australasia Pty Ltd</p> <p align="center">(New PBS listing)</p>	<p align="center">Infantile onset lysosomal acid lipase deficiency</p>	<p align="center">To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of infantile onset lysosomal acid lipase deficiency.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

<p align="center">Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p align="center">Drug Type and Use (What is the drug used to treat?)</p>	<p align="center">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.)</p>
<p align="center">SECUKINUMAB</p> <p>Solution for injection 300 mg in 2 mL pre-filled pen Solution for injection 300 mg in 2 mL pre-filled syringe</p> <p align="center">Cosentyx®</p> <p align="center">Novartis Pharmaceuticals Australia Pty Limited</p> <p align="center">(New PBS listing)</p>	<p align="center">Non-radiographic axial spondyloarthritis Severe active psoriatic arthritis Severe psoriatic arthritis Ankylosing spondylitis Active ankylosing spondylitis Severe chronic plaque psoriasis</p>	<p align="center">To request General Schedule Authority Required (Written) listings of new forms of secukinumab under the same indications as the currently listed 150 mg secukinumab pre-filled pen and prefilled syringe.</p>
<p align="center">SELINEXOR</p> <p align="center">Tablet 20 mg</p> <p align="center">Xpovio®</p> <p align="center">Antengene (Aus) Pty. Ltd.</p> <p align="center">(New PBS listing)</p>	<p align="center">Triple class refractory/penta-refractory multiple myeloma</p>	<p align="center">Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required listing, for use in combination with dexamethasone, for the treatment of adult patients with relapsed and/or refractory multiple myeloma, who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody.</p>
<p align="center">SELINEXOR</p> <p align="center">Tablet 20 mg</p> <p align="center">Xpovio®</p> <p align="center">Antengene (Aus) Pty. Ltd.</p> <p align="center">(New PBS listing)</p>	<p align="center">Relapsed and/or refractory multiple myeloma</p>	<p align="center">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.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

<p align="center">Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p align="center">Drug Type and Use (What is the drug used to treat?)</p>	<p align="center">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.)</p>
<p align="center">SEMAGLUTIDE</p> <p>Injection 0.25 mg in 0.5 mL pre-filled single dose pen Injection 0.5 mg in 0.5 mL pre-filled single dose pen Injection 1.0 mg in 0.5 mL pre-filled single dose pen Injection 1.7 mg in 0.75 mL pre-filled single dose pen Injection 2.4 mg in 0.75 mL pre-filled single dose pen</p> <p align="center">Wegovy®</p> <p>Novo Nordisk Pharmaceuticals Pty. Limited</p> <p align="center">(New PBS listing)</p>	<p align="center">Obesity</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of obesity.</p>
<p align="center">SOMAPACITAN</p> <p>Injection 10 mg in 1.5 mL pre-filled pen</p> <p align="center">Sogroya®</p> <p>Novo Nordisk Pharmaceuticals Pty. Limited</p> <p align="center">(New PBS listing)</p>	<p align="center">Adult growth hormone deficiency</p>	<p align="center">To request a Section 100 (Growth Hormone Program) Authority Required (Written) listing for the treatment of adult-onset growth hormone deficiency.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

<p align="center">Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p align="center">Drug Type and Use (What is the drug used to treat?)</p>	<p align="center">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.)</p>
<p align="center">SOMATROGON</p> <p>Injection 24 mg in 1.2 mL pre-filled single-use pen Injection 60 mg in 1.2 mL pre-filled single-use pen</p> <p align="center">Ngenla®</p> <p align="center">Pfizer Australia Pty Ltd</p> <p align="center">(New PBS listing)</p>	<p align="center">Paediatric growth hormone deficiency</p>	<p align="center">To request a Section 100 (Growth Hormone Program) Authority Required (Written) listing for the treatment of paediatric patients with growth hormone deficiency.</p>
<p align="center">SOTORASIB</p> <p align="center">Tablet 120 mg</p> <p align="center">Lumakras®</p> <p align="center">Amgen Australia Pty Limited</p> <p align="center">(New PBS listing)</p>	<p align="center">Non-small cell lung cancer</p>	<p align="center">To request a General Schedule Authority Required listing for the treatment of Kirsten rat sarcoma (KRAS) G12C variant non-squamous or not otherwise specified (NOS) stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer in patients who have progressed on prior therapy.</p>
<p align="center">TRIGLYCERIDES, MEDIUM CHAIN</p> <p align="center">Oral liquid 225 mL, 15 (K.Quik)</p> <p align="center">K.Quik®</p> <p align="center">Vitaflo Australia Pty Limited</p> <p align="center">(Change to PBS listing)</p>	<p align="center">Ketogenic diet</p>	<p align="center">To request a General Schedule Authority Required (STREAMLINED) listing of a new brand to replace the currently listed Betaquik brand.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

<p>Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p>Drug Type and Use (What is the drug used to treat?)</p>	<p>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.)</p>
<p>VERICIGUAT</p> <p>Tablet 2.5 mg Tablet 5 mg Tablet 10 mg</p> <p>Verquvo®</p> <p>Bayer Australia Ltd</p> <p>(New PBS listing)</p>	<p>Chronic heart failure</p>	<p>To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of symptomatic (NYHA class II, III or IV) chronic heart failure in patients with a reduced ejection fraction (left ventricular ejection fraction less than 45%) and who are stabilised after a recent decompensation heart failure event requiring hospitalisation and/or intravenous diuretic therapy.</p>
<p>ZANUBRUTINIB</p> <p>Capsule 80 mg</p> <p>Brukinsa®</p> <p>BeiGene Aus Pty Ltd</p> <p>(Change to recommended PBS listing)</p>	<p>Waldenstrom macroglobulinemia</p>	<p>Resubmission to request a General Schedule Authority Required listing for the treatment of adult patients with Waldenstrom macroglobulinemia.</p>
<p>AVELUMAB</p> <p>Injection 200 mg in 10 mL</p> <p>Bavencio®</p> <p>Merck Healthcare Pty Ltd</p> <p>(Sub-committee report DUSC Analysis)</p>	<p>Merkel cell carcinoma</p>	<p>To compare the predicted and actual utilisation of avelumab for Stage IV (metastatic) Merkel cell carcinoma since PBS listing.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

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.)
Breast cancer medicines All brands and strengths Various sponsors (Sub-committee report DUSC Analysis)	Breast cancer	To assess the utilisation of PBS listed medicines for treatment of locally advanced or metastatic breast cancer.
Disease modifying therapies for multiple sclerosis All brands and strengths Various sponsors (Sub-committee report DUSC Analysis)	Relapsing-remitting multiple sclerosis	To assess the utilisation of PBS listed disease modifying therapies for relapsing-remitting multiple sclerosis.
AMIFAMPRIDINE Tablet 10 mg Ruzurgi® The Trustee For Orspec Pharma Unit Trust (New PBS Listing)	Lambert-Eaton myasthenic syndrome	Resubmission to request a General Schedule Authority Required listing for the treatment of Lambert-Eaton myasthenic syndrome in adults and children aged six years and above.

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

<p>Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p>Drug Type and Use (What is the drug used to treat?)</p>	<p>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.)</p>
<p>DAPAGLIFLOZIN Tablet 10 mg Forxiga® AstraZeneca Pty Ltd (Change to PBS listing)</p>	<p>Chronic kidney disease</p>	<p>Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of chronic kidney disease.</p>
<p>GILTERITINIB Tablet 40 mg (as fumarate) Xospata® Astellas Pharma Australia Pty Ltd (New PBS listing)</p>	<p>Acute myeloid leukaemia</p>	<p>Resubmission to request a General Schedule Authority Required listing for the treatment of relapsed or refractory FMS-like tyrosine kinase 3 (FLT3) mutation-positive acute myeloid leukaemia.</p>
<p>MECASERMIN Solution for injection 40 mg in 4 mL vial Increlex® Ipsen Pty Ltd (New PBS listing)</p>	<p>Primary insulin-like growth factor 1 deficiency</p>	<p>Resubmission to request a Section 100 (Growth Hormone Program) Authority Required (Written) listing for the treatment of children and adolescents with growth failure due to primary insulin-like growth factor 1 deficiency.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

<p align="center">Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p align="center">Drug Type and Use (What is the drug used to treat?)</p>	<p align="center">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.)</p>
<p align="center">NIVOLUMAB</p> <p>Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL</p> <p align="center">Opdivo®</p> <p align="center">Bristol-Myers Squibb Australia Pty Ltd</p> <p align="center">(Change to PBS listing)</p>	<p align="center">Non-HER-2-positive gastric cancer, gastroesophageal junction cancer or oesophageal adenocarcinoma</p>	<p align="center">Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first-line treatment of patients with advanced or metastatic non-HER-2-positive gastric cancer, gastroesophageal junction cancer or oesophageal adenocarcinoma.</p>
<p align="center">PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p align="center">Keytruda®</p> <p align="center">Merck Sharp & Dohme (Australia) Pty Ltd</p> <p align="center">(Change to PBS listing)</p>	<p align="center">Squamous cell carcinoma of the head and neck (SCCHN)</p>	<p align="center">Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first-line treatment of recurrent or metastatic Squamous cell carcinoma of the head and neck (SCCHN).</p>
<p align="center">PEMBROLIZUMAB</p> <p>Solution concentrate for I.V. infusion 100 mg in 4 mL</p> <p align="center">Keytruda®</p> <p align="center">Merck Sharp & Dohme (Australia) Pty Ltd</p> <p align="center">(Change to PBS listing)</p>	<p align="center">Oesophageal carcinoma or HER-2-negative gastroesophageal junction adenocarcinoma</p>	<p align="center">Resubmission to request listing a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the first-line treatment of locally advanced or metastatic oesophageal carcinoma or HER-2-negative gastroesophageal junction adenocarcinoma.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

<p>Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p>Drug Type and Use (What is the drug used to treat?)</p>	<p>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.)</p>
<p>SACITUZUMAB GOVITECAN</p> <p>Powder for injection 180 mg</p> <p>Trodelvy®</p> <p>Gilead Sciences Pty Limited</p> <p>(New PBS listing)</p>	<p>Breast cancer</p>	<p>Resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing for the treatment of adult patients with unresectable, locally advanced or metastatic triple negative breast cancer, who have received two or more prior therapies, at least one of them in the locally advanced or metastatic setting.</p>
<p>TRIENTINE</p> <p>Tablet 150 mg (as tetrahydrochloride)</p> <p>Cuprior®</p> <p>Orphalan</p> <p>(New PBS listing)</p>	<p>Wilson disease</p>	<p>Resubmission to request a General Schedule Authority Required listing for the treatment of patients with Wilson disease who are intolerant to penicillamine.</p>
<p>TRIENTINE</p> <p>Capsule 250 mg (as dihydrochloride)</p> <p>Waymade®</p> <p>Clinect Pty Ltd</p> <p>(New PBS listing)</p>	<p>Wilson disease</p>	<p>Resubmission to request a General Schedule Authority Required (Written) listing for the treatment of patients with Wilson disease who are intolerant to penicillamine.</p>

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2022 PBAC MEETING**

Closing date for consumer comments 27th January 2022

<p align="center">Drug Name, form(s), strength(s) and Sponsor, Submission type (Drug name, form, strength, Trade name®, Sponsor, new listing/change to listing)</p>	<p align="center">Drug Type and Use (What is the drug used to treat?)</p>	<p align="center">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.)</p>
<p align="center">FLUOCINOLONE ACETONIDE</p> <p align="center">Intravitreal injection 190 micrograms</p> <p align="center">Iluvien®</p> <p align="center">Specialised Therapeutics Pharma Pty Ltd</p> <p align="center">(Review of positive PBAC recommendations not accepted by applicants)</p>	<p align="center">Diabetic macular oedema</p>	<p align="center">-</p>
<p align="center">MEPOLIZUMAB</p> <p align="center">Injection 100 mg in 1 mL prefilled syringe</p> <p align="center">Nucala®</p> <p align="center">GlaxoSmithKline Australia Pty Ltd</p> <p align="center">(Review of positive PBAC recommendations not accepted by applicants)</p>	<p align="center">Uncontrolled severe asthma</p>	<p align="center">-</p>

Version 6

Amendment

1. VENETOCLAX (Venclexta®) - removed.
2. NICOTINE REPLACEMENT THERAPY – removed.
3. PEMBROLIZUMAB (Keytruda®) for Squamous cell carcinoma of the head and neck (SCCHN) - added.
4. QUADRIVALENT INFLUENZA VACCINE (SURFACE ANTIGEN, INACTIVATED, CELL-BASED) - withdrawn
5. BIMEKIZUMAB (Bimelx®) for chronic plaque psoriasis – Purpose of submission for item amended.