PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
JULY 2021 PBAC MEETING

Closing date for consumer comments 26 May 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 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.

Submission type (new listing, change to listing)	**Drug Name, form(s), strength(s) and Sponsor** (Drug name, form, strength, Trade name®, Sponsor)	**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.)
Change to listing	ACALABRUTINIB Capsule 100 mg Calquence® Astrazeneca Pty Ltd	Relapsed and/or refractory mantle cell lymphoma (R/R MCL)	To request a General Schedule, Authority Required (online/telephone) listing for the treatment of patients with R/R MCL who have received at least one prior therapy or who have developed an intolerance to another Bruton's tyrosine kinase (BTK).
Change to listing	ADALIMUMAB Injection 20 mg in 0.4 mL pre-filled syringe Injection 40 mg in 0.8 mL pre-filled syringe Injection 40 mg in 0.8 mL pre-filled pen Abrilada® Pfizer Australia Pty Ltd	Severe Crohn disease; Moderate to severe ulcerative colitis; Severe active juvenile idiopathic arthritis; Complex refractory fistulising Crohn disease; Severe active rheumatoid arthritis; Severe psoriatic arthritis; Ankylosing spondylitis; Severe chronic plaque psoriasis; Moderate to severe hidradenitis suppurativa.	To request both General Schedule and Section 100 (Highly Specialised Drug Program) listing of adalimumab biosimilar under the same conditions as its reference biologic.

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Change to listing	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT METHIONINE Sachets containing oral powder 25 g, 30 HCU express 15 Vitaflo Australia Pty Ltd	Pyridoxine non-responsive homocystinuria	To request HCU Express 15 with new formulation continue to be listed on the PBS under existing conditions.
Change to listing	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE Sachets containing oral powder 34 g, 30 PKU express 20 Vitaflo Australia Pty Ltd	Phenylketonuria	To request PKU Express 20 with new formulation continue to be listed on the PBS under existing conditions.
Change to listing	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE Sachets containing oral powder 25 g, 30 PKU express 15 Vitaflo Australia Pty Ltd	Phenylketonuria	To request PKU Express 15 with new formulation continue to be listed on the PBS under existing conditions.

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Change to listing	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE AND TYROSINE Sachets containing oral powder 25 g, 30 TYR express 15 Vitaflo Australia Pty Ltd	Tyrosinaemia	To request TYR Express 15 with new formulation continue to be listed on the PBS under existing conditions.
Change to listing	AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE Sachets containing oral powder 25 g, 30 MSUD express 15 Vitaflo Australia Pty Ltd	Maple syrup urine disease	To request MSUD Express 15 with new formulation continue to be listed on the PBS under existing conditions.
Change to listing	BARICITINIB Tablet 2 mg Tablet 4 mg Olumiant® Eli Lilly Australia Pty Ltd	Severe atopic dermatitis	To request a General Schedule, Authority Required (written) listing for the treatment of patients with severe atopic dermatitis.

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Change to listing	BORTEZOMIB Powder for injection 2.5 mg Bortezomib Juno Juno Pharmaceuticals Pty Ltd	Multiple Myeloma	To request a Section 100 (Efficient Funding of Chemotherapy Program) listing of a new bortezomib brand with an additional strength under the same conditions as the currently listed brand.
Change to listing	BORTEZOMIB Powder for injection 1 mg Powder for injection 2.5 mg Powder for injection 3 mg Powder for injection 3.5 mg DBL Bortezomib Pfizer Australia Pty Ltd	Multiple Myeloma	To request a Section 100 (Efficient Funding of Chemotherapy Program) listing of a new bortezomib brand with an additional strength under the same conditions as the currently listed brand.
New listing	BUDESONIDE + GLYCOPYRRONIUM + FORMOTEROL Pressurised inhalation containing budesonide 160 micrograms with glycopyrronium 7.2 micrograms (as bromide) and formoterol fumarate dihydrate 5 micrograms per dose, 120 doses Breztri Aerosphere Astrazeneca Pty Ltd	Moderate to severe chronic obstructive pulmonary disease (COPD)	To request a General Schedule, Authority Required (STREAMLINED) listing for the treatment of moderate to severe COPD.

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Change to listing	DAPAGLIFLOZIN Tablet 10 mg Forxiga® AstraZeneca Pty Ltd	Chronic kidney disease	To request a General Schedule, Authority Required (STREAMLINED) listing for the treatment of chronic kidney disease.
Change to listing	DAPAGLIFLOZIN Tablet 10 mg Forxiga® AstraZeneca Pty Ltd	Heart failure	Resubmission to request a General Schedule, Authority Required (STREAMLINED) listing for the treatment of heart failure with reduced ejection fraction.
Change to listing	DARATUMUMAB Solution for subcutaneous injection 1,800 mg in 15 mL vial Darzalex® Janssen-Cilag Pty Ltd	Relapsed and/or refractory multiple myeloma (RRMM)	To request a Section 100 (Highly Specialised Drugs Program), Authority Required (online/telephone) listing of a new 1,800 mg subcutaneous flat dosing regimen in addition to the current 16 mg/kg intravenous weight-based dosing regimen for the treatment of RRMM.
New listing	ELOTUZUMAB Powder for I.V. infusion 300 mg Powder for I.V. infusion 400 mg Empliciti® Bristol-Myers Squibb Australia Pty Ltd	Relapsed and/or refractory multiple myeloma (RRMM)	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy), Authority Required (telephone/online) listing, in combination with lenalidomide and dexamethasone, for the treatment of RRMM.

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New listing	ESKETAMINE Nasal spray solution 28 mg Spravato® Janssen-Cilag Pty Ltd	Treatment resistant depression	To request a Section 100 (Highly Specialised Drugs Program), Authority Required (telephone) listing for the treatment of treatment resistant depression, in combination with a newly initiated oral antidepressant.
Change to listing	ETANERCEPT Injection 50 mg in 1 mL single use dose-dispenser cartridge, 4 Enbrel® Pfizer Australia Pty Ltd	Rheumatoid arthritis; Plaque psoriasis; Ankylosing spondylitis; Psoriatic arthritis; Juvenile idiopathic arthritis; Paediatric plaque psoriasis.	To request both General Schedule and Section 100 (Highly Specialised Drugs Program) listings of etanercept in dose dispenser cartridges under the same conditions as the currently listed pre-filled syringes.
Change to listing	FOLLITROPIN ALFA Injection 300 I.U. in 0.5 mL multi-dose cartridge Injection 450 I.U. in 0.75 mL multi-dose cartridge Injection 900 I.U. in 1.5 mL multi-dose cartridge Ovaleap® Theramex Australia Pty Ltd	Assisted Reproductive Technology; Anovulatory infertility; Infertility.	To request both General Schedule and Section 100 (IVF Program) listings of a biosimilar under the same conditions as its reference biologic.

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Change to listing	HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE Oral liquid 250 mL, 30 KetoVie® Peptide 4:1 Cortex Health Pty Ltd	Ketogenic diet	To present additional data to progress the November 2020 recommended listing for KetoVie Peptide 4:1.
Change to listing	HYDROCORTISONE Capsule 0.5 mg Capsule 1 mg Capsule 2 mg Capsule 5 mg Alkindi® Chiesi Australia Pty Ltd	Adrenal Insufficiency	To request an Authority Required (STREAMLINED) listing for replacement therapy of adrenal insufficiency for patients aged six or younger.
Change to listing	HYPROMELLOSE Eye drops 3 mg per mL, 10 mL Revive Tears® Petrus Pharmaceuticals Pty Ltd	Severe dry eye syndrome, including Sjogren's syndrome	To request a Restricted benefit listing of a new brand under the same conditions as the currently listed hypromellose eye drops; and to seek advice on therapeutic bioequivalence.

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New listing WITHDRAWN	INCLISIRAN Injection 284 mg in 1.5 mL pre-filled syringe Leqvio® Novartis Pharmaceuticals Australia Pty Ltd	Hypercholesterolaemia	To request a General Schedule, Authority Required (online/telephone) listing for the treatment of heterozygous familial hypercholesterolaemia, and non-familial hypercholesterolaemia with atherosclerotic cardiovascular disease.
New listing	LANADELUMAB Solution for subcutaneous injection 300 mg in 2 mL Takhzyro® Takeda Pharmaceuticals Australia Pty Ltd	Hereditary angioedema	Resubmission to request an Authority Required (telephone/online) listing for the prevention of recurrent attacks of hereditary angioedema (C1-esterase inhibitor deficiency or dysfunction) in patients aged 12 years and older.
Change to listing	LORLATINIB Tablet 25 mg Tablet 100 mg Lorviqua® Pfizer Australia Pty Ltd	Locally advanced (stage IIIB) or metastatic (stage IV) anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC)	To request a General Schedule, Authority Required (online/telephone) listing for the treatment of locally advanced (Stage IIIB) or metastatic (Stage IV) ALK-positive NSCLC in patients who have not received prior treatment with an ALK inhibitor.
–	LUMACAFTOR + IVACAFTOR Tablet containing lumacaftor 100 mg with ivacaftor 125 mg Orkambi® Vertex Pharmaceuticals (Australia) Pty. Ltd.	Cystic fibrosis	To provide additional data as specified in the Deed of Supply.

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Change to listing	METHOXSALEN Solution for blood fraction 20 microgram per mL, 10 mL Uvadex® Terumo Bct Australia Pty Ltd	Steroid dependent or steroid intolerant or steroid refractory chronic graft versus host disease (cGVHD)	To request a Section 100 (Highly Specialised Drugs Program), Authority Required (STREAMLINED) listing for the treatment of patients with steroid dependent or steroid intolerant or steroid refractory cGVHD, as part of treatment with integrated, closed system, extracorporeal photopheresis.
New listing	NIRAPARIB Capsule 100 mg Zejula® Glaxosmithkline Australia Pty Ltd	High grade epithelial ovarian, fallopian tube, or primary peritoneal cancer	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 (HGEOC) that is responsive (complete/partial) to platinum-based chemotherapy.
Change to listing	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	Second-line squamous cell oesophageal carcinoma (2L OSCC)	To request a Section 100 (Efficient Funding of Chemotherapy), Authority Required (STREAMLINED) listing for 2L OSCC that have failed treatment with a fluoropyrimidine and platinum containing treatment regimen.
Change to listing	NUSINERSEN Solution for injection 12.6 mg in 5 mL Spinraza® Biogen Australia Pty Ltd	Spinal muscular atrophy (SMA)	Resubmission to extend the current Section 100 (Highly Specialised Drugs Program), Authority Required (written) listing to include adults with SMA.

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New listing	OPICAPONE Capsule 50 mg Ongentys® Maxx Pharma Pty Ltd	Parkinson Disease (PD)	To request a General Schedule, Restricted benefit listing for the treatment of PD, as adjunctive therapy to levodopa-decarboxylase inhibitor combinations in patients motor function fluctuations due to end-of-dose effects.
Change to listing	PALBOCICLIB Tablet 75 mg Tablet 100 mg Tablet 125 mg Ibrance® Pfizer Australia Pty Ltd	Hormone receptor-positive (HR+), human epidermal growth factor receptor-2 negative (HER2-) advanced or metastatic breast cancer	To request an Authority Required listing of palbociclib tablets under the same conditions as the already listed capsules.
New listing	RAVULIZUMAB Solution concentrate for I.V. infusion 300 mg in 3 mL Solution concentrate for I.V. infusion 1,100 mg in 11 mL Ultomiris® Alexion Pharmaceuticals Australasia Pty Ltd	Paroxysmal nocturnal haemoglobinuria (PNH)	Resubmission to request a Section 100 (Highly Specialised Drugs Program), Authority Required (written) listing for the treatment of adults with paroxysmal nocturnal haemoglobinuria (PNH).

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Change to listing	SECUKINUMAB Injection 150 mg in 1 mL pre-filled pen Cosentyx® Novartis Pharmaceuticals Australia Pty Ltd	Ankylosing spondylitis	To request an increase in the maximum quantity to 2 and a reduction in the number of repeats from 5 to 2.
New listing	SELINEXOR Tablet 20 mg Xpovio® Antengene (Aus) Pty. Ltd.	Relapsed and/or refractory multiple myeloma	To request a Section 100 (Highly Specialised Drugs Program), Authority Required (STREAMLINED) listing, in combination with bortezomib and dexamethasone, for the treatment of relapsed and/or refractory multiple myeloma.
New listing	SELINEXOR Tablet 20 mg Xpovio® Antengene (Aus) Pty. Ltd.	Triple class refractory/penta-refractory multiple myeloma (TCR/PR MM)	To request a Section 100 (Highly Specialised Drugs Program), Authority Required (STREAMLINED) listing, in combination with dexamethasone, for the treatment of TCR/PR MM in patients who have received at least four prior therapies.
New listing	SELINEXOR Tablet 20 mg Xpovio® Antengene (Aus) Pty. Ltd.	Relapsed and/or refractory diffuse large B-cell lymphoma (DLBCL)	To request a Section 100 (Highly Specialised Drugs Program), Authority Required (STREAMLINED) listing for the treatment of relapsed and/or refractory DLBCL in patients who have received at least two lines of systemic therapy.

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New listing	SILTUXIMAB Powder for injection 100 mg Powder for injection 400 mg Sylvant® Eusa Pharma (UK) Ltd	Idiopathic multicentric Castleman's disease (iMCD)	To request a Section 100 (Highly Specialised Drugs Program), Authority Required (online/telephone) listing for the treatment of iMCD.
New listing	TRABECTEDIN Powder for I.V. infusion 0.25 mg Powder for I.V. infusion 1 mg Yondelis® Specialised Therapeutics Pharma Pty Ltd	Advanced (unresectable and/or metastatic) leiomyosarcoma	To request a Section 100 (Efficient Funding of Chemotherapy), Authority Required (STREAMLINED) listing for the treatment of unresectable or metastatic leiomyosarcoma following a prior anthracycline-containing regimen.
Change to listing	TRIPTORELIN Powder for I.M. injection (prolonged release) 22.5 mg (as embonate), with solvent Diphereline® Ipsen Pty Ltd	Central precocious puberty (CPP)	To request a General Schedule, Restricted Benefit listing for the treatment of CPP.
Change to listing	UPADACITINIB Tablet 15 mg Tablet 30 mg Rinvoq® Abbvie Pty Ltd	Severe atopic dermatitis	To request a General Schedule, Authority Required (telephone) listing for the treatment of severe atopic dermatitis.

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New listing	ZANUBRUTINIB Capsule 80 mg Brukinsa® BeiGene Aus Pty Ltd	Waldenstrom macroglobulinemia	To request a General Schedule, Authority Required (telephone) listing for the treatment of adult patients with Waldenstrom macroglobulinemia.
New listing	ZANUBRUTINIB Capsule 80 mg Brukinsa® BeiGene Aus Pty Ltd	Relapsed and/or refractory mantle cell lymphoma	To request a General Schedule, Authority Required (telephone) listing for the treatment of relapsed and/or refractory mantle cell lymphoma.
Sub-committee report (DUSC Analysis)	GUANFACINE Intuniv® Takeda Pharmaceuticals Australia Pty Ltd	Treatment of attention deficit hyperactivity disorder (ADHD)	To compare the predicted and actual utilisation of guanfacine for the treatment of ADHD since PBS listing.
Sub-committee report (DUSC Analysis)	EVOLOCUMAB Repatha® Amgen Australia Pty Limited	Treatment of heterozygous familial hypercholesterolaemia (FH)	To compare the predicted and actual utilisation of evolocumab for the treatment of heterozygous FH since PBS listing.
Sub-committee report (DUSC Analysis)	SOMATROPIN Multiple brands and sponsors	Treatment of short stature and slow growth	To assess the utilisation of PBS listed somatropin for the treatment of short stature and slow growth.

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Review of positive PBAC recommendations not accepted by applicants	BUDESONIDE Capsule 3 mg Entocort® Chiesi Australia Pty Ltd	Mild to Moderate Crohn Disease	–
Review of positive PBAC recommendations not accepted by applicants	ENOXAPARIN Injection 120 mg in 0.8 mL pre-filled syringe Injection 150 mg in 1 mL pre-filled syringe Clexane Forte®; Enoxaparin Winthrop®; Clexane Forte Safety-Lock® Sanofi-Aventis Australia Pty Ltd	Unrestricted benefit	–
Review of positive PBAC recommendations not accepted by applicants	RAMUCIRUMAB 100 mg in 10 mL vial 500 mg in 50 mL vial Cyramza® Eli Lilly Australia Pty Ltd	Advanced gastric or gastro-oesophageal junction adenocarcinoma	–
Review of positive PBAC recommendations not accepted by applicants	SECUKINUMAB 150 mg /mL powder for injection 150 mg/mL pre-filled syringe Cosentyx® Novartis Pharmaceuticals Australia Pty Ltd	Severe chronic plaque psoriasis	–

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Review of positive PBAC recommendations not accepted by applicants	SEVELAMER Powder for oral liquid, 2.4g Renvela® Sanofi-Aventis Australia Pty Ltd	Chronic kidney disease	–
Review of positive PBAC recommendations not accepted by applicants	TENOFOVIR ALAFENAMIDE Tablet 25 mg Vemlidy® Gilead Sciences	Chronic hepatitis B	–
Review of positive PBAC recommendations not accepted by applicants	TRIGLYCERIDES MEDIUM CHAIN FORMULA Oral liquid 500mL, 12 Nutrini Peptisorb® Nutricia Australia Pty Ltd	Change to pack size/quantities	–
New listing	DAROLUTAMIDE Tablet 300 mg Nubeqa® Bayer Australia Limited	Castration resistant carcinoma of the prostate	Resubmission to request an Authority Required (Telephone) listing for the treatment of castration resistant carcinoma of the prostate.

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New listing	DECITABINE WITH CEDAZURIDINE Tablet containing decitabine 35 mg + cedazuridine 100 mg Inqovi® Otsuka Australia Pharmaceutical Pty. Ltd	High risk myelodysplastic syndromes (MDS) and chronic myelomonocytic leukaemia (CMML)	Resubmission to request an Authority Required (non-immediate/delayed) - In Writing only/Electronic listing for the treatment of high-risk myelodysplastic syndrome and chronic myelomonocytic leukaemia.
New listing	MELATONIN Tablet 1 mg Tablet 5 mg Slenyto® Aspen Pharmacare Australia Pty Ltd	Insomnia	Resubmission to request an Authority Required (Telephone) listing for the treatment of insomnia in patients between the ages of 2 to 18 with Smith-Magenis syndrome.
New listing	RIPRETINIB Tablet 50 mg Qinlock® Specialised Therapeutics PM Pty Ltd	Gastrointestinal stromal tumour	Resubmission to request an Authority Required (Written) listing for the treatment of metastatic or unresectable malignant gastrointestinal stromal tumour.
Change to listing	VENETOCLAX Tablet 50 mg Tablet 100 mg Venclexta® AbbVie Pty Ltd	Acute myeloid leukaemia	Resubmission to request a General Schedule - Authority Required (telephone/online) listing for the treatment of patients with newly diagnosed acute myeloid leukaemia, who are ineligible for standard intensive remission induction chemotherapy.

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Change to listing	ENZALUTAMIDE Capsule 40 mg Xtandi® Astellas Pharma Australia Pty Ltd ABIRATERONE Tablet 250 mg Tablet 500 mg Zytiga® Janssen-Cilag Pty Ltd	Castration resistant carcinoma of the prostate	Request by the PBAC to consider changing the PBS indication for these items from metastatic castration resistant carcinoma of the prostate to castration resistant carcinoma of the prostate.

Version 4

Amendment

1. INCLISIRAN agenda item has been withdrawn.

Items added or amended previously (Version 2, 3)

- Added – ENZALUTAMIDE and ABIRATERONE.
- Added – Five (5) Early Re-entry resubmissions received (pages 17–18).
- Added – Seven (7) items scheduled for review under the process for reviewing positive PBS-listing recommendations not accepted by applicants (pages 15–17).
- Amended – NIVOLUMAB (Advanced or metastatic non-HER2 positive gastro-oesophageal junction cancer or oesophageal adenocarcinoma) agenda item was withdrawn.
- Amended – DAPAGLIFLOZIN (Heart failure), NUSINERSEN and RAVULIZUMAB: *resubmission* added to 'purpose of submission'.
- Amended – ETANERCEPT: deleted *Non-radiographic Axial Spondyloarthritis*, replaced with *Psoriatic arthritis*.
- Amended – SELINEXOR: (for all three agenda items) deleted *20mg*, replaced with *200mg*.
- Amended – RAVULIZUMAB: deleted *Solution for I.V. infusion 300 mg in 3 mL*, replaced with *Solution concentrate for I.V. infusion 300 mg in 3 mL and Solution concentrate for I.V. infusion 1,100 mg in 11 mL*.