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| 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.   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](https://www.pbs.gov.au/info/industry/listing/listing-steps).  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](https://www.pbs.gov.au/info/industry/useful-resources/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.) |
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| 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. |
| APREMILAST   Tablet 30 mg  Pack containing 4 tablets 10 mg, 4 tablets 20 mg and 19 tablets 30 mg   Otezla®  Amgen Australia Pty Limited  (Change to PBS listing) | Severe chronic plaque psoriasis | 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. |
| BECLOMETASONE WITH FORMETEROL  Pressurised inhalation containing beclometasone dipropionate 100 micrograms and formoterol fumarate dihydrate 6 micrograms per dose, 120 dose  Fostair®  Chiesi Australia Pty Ltd  (Change to PBS listing) | Chronic obstructive pulmonary disease | 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. |
| BECLOMETASONE WITH FORMOTEROL AND GLYCOPYRRONIUM  Pressurised inhalation containing beclometasone dipropionate 100 micrograms with formoterol fumarate dihydrate 6 micrograms and glycopyrronium 10 micrograms (as bromide) per dose, 120 doses Pressurised inhalation containing beclometasone dipropionate 200 micrograms with formoterol fumarate dihydrate 6 micrograms and glycopyrronium 10 micrograms (as bromide) per dose, 120 doses  Trimbow®  Chiesi Australia Pty Ltd  (New PBS listing) | Asthma | 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. |
| BEVACIZUMAB   Solution for I.V. infusion 100 mg in 4 mL Solution for I.V. infusion 400 mg in 16 mL  Bevaciptin®  Cipla Australia Pty Ltd  (New PBS listing) | Cancers | 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. |
| BIMEKIZUMAB   Solution for injection 160 mg in 1 mL pre-filled pen Solution for injection 160 mg in 1 mL pre-filled syringe  Bimzelx®  UCB Australia Proprietary Limited  (New PBS listing) | Plaque psoriasis | To request a General Schedule Authority Required (Written) listing for the treatment of adults with severe plaque psoriasis. |
| BORTEZOMIB   Solution for injection 2.5 mg Solution for injection 3.5 mg  Bortezomib Ever Pharma®  Interpharma Pty Ltd  (New PBS listing) | Multiple Myeloma | 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. |
| 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  (New PBS listing) | X-linked hypophosphataemia | Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of X-linked hypophosphataemia. |
| CABAZITAXEL   Solution concentrate for I.V. infusion 60 mg in 3 mL  Cabazitaxel Accord®  Accord Healthcare Pty. Ltd.  (New PBS listing) | Prostate cancer | 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. |
| CANNABIDIOL   Oral liquid 100 mg per mL, 100 mL  Epidyolex®  Chiesi Australia Pty Ltd  (Change to PBS listing) | Lennox-Gastaut syndrome | 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. |
| CARFILZOMIB   Powder for injection 10 mg Powder for injection 30 mg Powder for injection 60 mg  Kyprolis®  Amgen Australia Pty Limited  (Change to PBS listing) | Multiple myeloma | 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. |
| CEMIPLIMAB  Solution for I.V. infusion 350 mg in 7 mL  Libtayo®  Sanofi-aventis Australia Pty Ltd  (New PBS listing) | Squamous cell carcinoma | 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. |
| CICLOSPORIN  Eye drops 900 micrograms per mL, single dose units, 0.25 mL, 60  Cequa®  Sun Pharma ANZ Pty Ltd  (New PBS listing) | Chronic severe dry eye disease with keratitis | 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. |
| DIPTHERIA, TETANUS, PERTUSSIS, HEPATITIS B, POLIOMYELITIS AND HAEMOPHILUS INFLUENZAE TYPE B CONJUGATE VACCINE (DTaP-HB-IPV-Hib)   0.5 mL pre-filled syringe  Vaxelis®  sanofi-aventis Australia Pty Ltd  (New listing) | Diptheria, tetanus, pertussis, hepatitis B, poliomyelitis and Haemophilus influenzae type b | To request National Immunisation Program listing for the prevention of diptheria, tetanus, pertussis, hepatitis B, poliomyelitis and Haemophilus influenzae type b. |
| DIROXIMEL FUMARATE  Capsule 231 mg  Vumerity®  Biogen Australia Pty Ltd  (New PBS listing) | Multiple sclerosis | To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of relapsing-remitting multiple sclerosis. |
| DORZOLAMIDE WITH TIMOLOL  Eye drops containing dorzolamide 20 mg (as hydrochloride) with timolol 5 mg (as maleate) per mL, 5 mL  VIzo-PF Dorzolatim®  Aft Pharmaceuticals (Au) Pty Ltd  (New PBS listing) | Elevated intra-ocular pressure | 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. |
| DOSTARLIMAB   Solution concentrate for I.V. infusion 500 mg in 10 mL  Jemperli®  GlaxoSmithKline Australia Pty Ltd  (New PBS listing) | Endometrial cancer | 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. |
| DULAGLUTIDE  Injection 3 mg in 0.5 mL single dose pre-filled pen  Injection 4.5 mg in 0.5 mL single dose pre-filled pen  Trulicity®  Eli Lilly Australia Pty Ltd  (New PBS listing) | Type 2 diabetes mellitus | 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. |
| DUPILUMAB   Injection 200 mg in 1.14 mL single dose pre-filled syringe Injection 300 mg in 2 mL single dose pre-filled syringe  Dupixent®  sanofi-aventis Australia Pty Ltd  (Change to PBS listing) | Atopic dermatitis | To request a General Schedule Authority Required listing for the treatment of severe atopic dermatitis in patients aged 6 to 11 years. |
| DURVALUMAB   Solution concentrate for I.V. infusion 500 mg in 10 mL  Imfinzi®  AstraZeneca Pty Ltd  (Change to PBS listing) | Unresectable Stage III, non-small cell lung cancer | 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. |
| ENFORTUMAB VEDOTIN  Powder for I.V. infusion 20 mg Powder for I.V. infusion 30 mg  Padcev®  Astellas Pharma Australia Pty Ltd  (New PBS listing) | Urothelial cancer | 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. |
| 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. |
| GALCANEZUMAB   Injection 120 mg in 1 mL pre-filled pen  Emgality®  Eli Lilly Australia Pty Ltd  (Change to PBS listing) | Migraine | Resubmission to extend the current General Schedule Authority Required (STREAMLINED) listing to include treatment-resistant high frequency episodic migraine. |
| GLATIRAMER   Injection containing glatiramer acetate 40 mg in 1 mL single dose pre-filled pen  Copaxone®  Teva Pharma Australia Pty Ltd  (New PBS listing) | Multiple sclerosis | 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. |
| GLYCOMACROPEPTIDE FORMULA WITH AMINO ACIDS, CARBOHYDRATES, MINERALS AND LOW PHENYLALANINE  Sachets containing oral powder 12.5 g, 30 (PKU GMPro Mix-In)  PKU GMPro MIX-IN®  Nutricia Australia Pty Limited  (New PBS listing) | Phenylketonuria | To request a General Schedule Restricted Benefit listing for treatment of phenylketonuria in patients older than 3 years of age. |
| GLYCOMACROPEPTIDE FORMULA WITH AMINO ACIDS, VITAMINS, MINERALS, TRACE ELEMENTS, CARBOHYDRATE, FAT AND LOW PHENYLALANINE  Sachets containing oral powder 33.4 g, 30(PKU GMPro ULTRA)  PKU GMPro ULTRA®  Nutricia Australia Pty Limited  (New PBS listing) | Phenylketonuria | To request a General Schedule Restricted Benefit listing for treatment of phenylketonuria in patients older than 3 years of age. |
| INFLIXIMAB   Solution for injection 120 mg in 1 mL pre-filled pen Solution for injection 120 mg in 1 mL pre-filled syringe  Remsima® SC  Celltrion Healthcare Australia Pty Ltd  (New PBS listing) | Ankylosing spondylitis Psoriatic arthritis Chronic plaque psoriasis Refractory fistulising Crohn Disease | To request a General Schedule Authority Required listing for the treatment of ankylosing spondylitis, psoriatic arthritis, chronic plaque psoriasis and refractory fistulising Crohn Disease. |
| IXAZOMIB   Capsule 2.3 mg  Capsule 3 mg Capsule 4 mg  Ninlaro®  Takeda Pharmaceuticals Australia Pty. Ltd.  (New PBS listing) | Multiple myeloma | 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. |
| METHYLPHENIDATE   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)   Ritalin® LA  Novartis Pharmaceuticals Australia Pty Limited  (Change to PBS listing) | Attention deficit hyperactivity disorder | 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. |
| NIRAPARIB   Capsule 100 mg  Zejula®  GlaxoSmithKline Australia Pty Ltd  (New PBS listing) | High grade epithelial ovarian, fallopian tube, or primary peritoneal cancer | 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. |
| 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) | Second-line squamous cell  oesophageal carcinoma | 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. |
| NUSINERSEN   Solution for injection 12 mg in 5 mL  Spinraza®  Biogen Australia Pty Ltd  (Change to PBS listing) | Spinal muscular atrophy | 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). |
| OZANIMOD   Capsule 920 micrograms Pack containing 4 capsules 230 micrograms and 3 capsules 460 micrograms  Zeposia®  Celgene Pty Limited  (Change to PBS listing) | Ulcerative colitis | To request a General Schedule Authority Required (Written) listing for the treatment of moderate to severe ulcerative colitis. |
| PALBOCICLIB   Tablet 75 mg Tablet 100 mg Tablet 125 mg  Ibrance®  Pfizer Australia Pty Ltd  (Change to recommended PBS listing) | Breast cancer | 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. |
| PALIPERIDONE  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  Invega Hafyera®  Janssen-Cilag Pty Ltd  (New PBS listing) | Schizophrenia | 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. |
| PEGCETACOPLAN   Solution for subcutaneous infusion 1,080 mg in 20 mL   Empaveli™  Swedish Orphan Biovitrum Pty Ltd  (New PBS listing) | Paroxysmal nocturnal haemoglobinuria | 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. |
| PEMBROLIZUMAB   Solution concentrate for I.V. infusion 100 mg in 4 mL  Keytruda®  Merck Sharp & Dohme (Australia) Pty Ltd  (Change to PBS listing) | Renal cell carcinoma | 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. |
| PEMBROLIZUMAB  Solution concentrate for I.V. infusion 100 mg in 4 mL  Keytruda®  Merck Sharp & Dohme (Australia) Pty Ltd  (Change to PBS listing) | Endometrial cancer | 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. |
| QUADRIVALENT INFLUENZA VACCINE (SURFACE ANTIGEN, INACTIVATED, CELL-BASED)  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  Flucelvax® Quad  Seqirus (Australia) Pty Ltd  (New listing)  WITHDRAWN | Prevention of influenza | To request National Immunisation Program listing for the prevention of influenza. |
| RABEPRAZOLE   Tablet containing rabeprazole sodium 20 mg (enteric coated)  Pariet®  Janssen-Cilag Pty Ltd  (Change to PBS listing) | Complex gastro-oesophageal reflux disease  Scleroderma oesophagus Gastro-oesophageal reflux disease Peptic ulcer | 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). |
| RANIBIZUMAB   Solution for ocular implant 39.5 mg in 0.395 mL  Susvimo®  Roche Products Pty Ltd  (New PBS listing) | Neovascular (wet) age-related macular degeneration | 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. |
| RISANKIZUMAB   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  Skyrizi®  AbbVie Pty Ltd  (Change to PBS listing) | Severe chronic plaque psoriasis | 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. |
| RISANKIZUMAB   Injection 150 mg in 1 mL pre-filled syringe Injection 150 mg in 1 mL pre-filled pen  Skyrizi®  AbbVie Pty Ltd  (New PBS listing) | Psoriatic arthritis | To request a General Schedule Authority Required (Written) listing for the treatment of severe psoriatic arthritis. |
| SEBELIPASE ALFA  Solution concentrate for I.V. infusion 20 mg in 10 mL  Kanuma®  Alexion Pharmaceuticals Australasia Pty Ltd  (New PBS listing) | Infantile onset lysosomal acid lipase deficiency | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of infantile onset lysosomal acid lipase deficiency. |
| SECUKINUMAB  Solution for injection 300 mg in 2 mL pre-filled pen Solution for injection 300 mg in 2 mL pre-filled syringe  Cosentyx®  Novartis Pharmaceuticals Australia Pty Limited  (New PBS listing) | Non-radiographic axial spondyloarthritis Severe active psoriatic arthritis Severe psoriatic arthritis Ankylosing spondylitis Active ankylosing spondylitis Severe chronic plaque psoriasis | 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. |
| SELINEXOR  Tablet 20 mg  Xpovio®  Antengene (Aus) Pty. Ltd.  (New PBS listing) | Triple class refractory/penta-refractory multiple myeloma | 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. |
| SELINEXOR  Tablet 20 mg  Xpovio®  Antengene (Aus) Pty. Ltd.  (New PBS listing) | Relapsed and/or refractory multiple myeloma | Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required listing, for use in combination with bortezomib and dexamethasone, for the treatment of relapsed and/or refractory multiple myeloma. |
| SEMAGLUTIDE   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  Wegovy®  Novo Nordisk Pharmaceuticals Pty. Limited  (New PBS listing) | Obesity | To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of obesity. |
| SOMAPACITAN   Injection 10 mg in 1.5 mL pre-filled pen  Sogroya®  Novo Nordisk Pharmaceuticals Pty. Limited  (New PBS listing) | Adult growth hormone deficiency | To request a Section 100 (Growth Hormone Program) Authority Required (Written) listing for the treatment of adult-onset growth hormone deficiency. |
| SOMATROGON   Injection 24 mg in 1.2 mL pre-filled single-use pen Injection 60 mg in 1.2 mL pre-filled single-use pen  Ngenla®  Pfizer Australia Pty Ltd  (New PBS listing) | Paediatric growth hormone deficiency | To request a Section 100 (Growth Hormone Program) Authority Required (Written) listing for the treatment of paediatric patients with growth hormone deficiency. |
| SOTORASIB  Tablet 120 mg  Lumakras®  Amgen Australia Pty Limited  (New PBS listing) | Non-small cell lung cancer | 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. |
| TRIGLYCERIDES, MEDIUM CHAIN  Oral liquid 225 mL, 15 (K.Quik)  K.Quik®  Vitaflo Australia Pty Limited  (Change to PBS listing) | Ketogenic diet | To request a General Schedule Authority Required (STREAMLINED) listing of a new brand to replace the currently listed Betaquik brand. |
| VERICIGUAT   Tablet 2.5 mg Tablet 5 mg Tablet 10 mg  Verquvo®  Bayer Australia Ltd  (New PBS listing) | Chronic heart failure | 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. |
| ZANUBRUTINIB   Capsule 80 mg  Brukinsa®  BeiGene Aus Pty Ltd  (Change to recommended PBS listing) | Waldenstrom macroglobulinemia | Resubmission to request a General Schedule Authority Required listing for the treatment of adult patients with Waldenstrom macroglobulinemia. |
| AVELUMAB  Injection 200 mg in 10 mL  Bavencio®  Merck Healthcare Pty Ltd  (Sub-committee report  DUSC Analysis) | Merkel cell carcinoma | To compare the predicted and actual utilisation of avelumab for Stage IV (metastatic) Merkel cell carcinoma since PBS listing. |
| 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. |
| DAPAGLIFLOZIN  Tablet 10 mg  Forxiga®  AstraZeneca Pty Ltd  (Change to PBS listing) | Chronic kidney disease | Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of chronic kidney disease. |
| GILTERITINIB  Tablet 40 mg (as fumarate)  Xospata®  Astellas Pharma Australia Pty Ltd  (New PBS listing) | Acute myeloid leukaemia | 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. |
| MECASERMIN  Solution for injection 40 mg in 4 mL vial  Increlex®  Ipsen Pty Ltd  (New PBS listing) | Primary insulin-like growth factor 1 deficiency | 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. |
| 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) | Non-HER-2-positive gastric cancer, gastroesophageal junction cancer or oesophageal adenocarcinoma | 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. |
| PEMBROLIZUMAB  Solution concentrate for I.V. infusion 100 mg in 4 mL  Keytruda®  Merck Sharp & Dohme (Australia) Pty Ltd  (Change to PBS listing) | Squamous cell carcinoma of the head and neck (SCCHN) | 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). |
| PEMBROLIZUMAB  Solution concentrate for I.V. infusion 100 mg in 4 mL  Keytruda®  Merck Sharp & Dohme (Australia) Pty Ltd  (Change to PBS listing) | Oesophageal carcinoma or HER-2-negative gastroesophageal junction adenocarcinoma | 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. |
| SACITUZUMAB GOVITECAN  Powder for injection 180 mg  Trodelvy®  Gilead Sciences Pty Limited  (New PBS listing) | Breast cancer | 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. |
| TRIENTINE  Tablet 150 mg (as tetrahydrochloride)  Cuprior®  Orphalan  (New PBS listing) | Wilson disease | Resubmission to request a General Schedule Authority Required listing for the treatment of patients with Wilson disease who are intolerant to penicillamine. |
| TRIENTINE  Capsule 250 mg (as dihydrochloride)  Waymade®  Clinect Pty Ltd  (New PBS listing) | Wilson disease | Resubmission to request a General Schedule Authority Required (Written) listing for the treatment of patients with Wilson disease who are intolerant to penicillamine. |
| FLUOCINOLONE ACETONIDE  Intravitreal injection 190 micrograms  Iluvien®  Specialised Therapeutics Pharma Pty Ltd  (Review of positive PBAC recommendations not accepted by applicants) | Diabetic macular oedema | - |
| MEPOLIZUMAB  Injection 100 mg in 1 mL prefilled syringe  Nucala®  GlaxoSmithKline Australia Pty Ltd  (Review of positive PBAC recommendations not accepted by applicants) | Uncontrolled severe asthma | - |

**Version 6**

Amendment

* + - * 1. VENETOCLAX (Venclextra®) - removed.
        2. NICTOTINE REPLACEMENT THERAPHY – 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.