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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 Chair’s report (verbal)**  **3 Matters arising from the minutes**  **4 Matters arising/outstanding**  **5 New drug applications**  **6 Requests for changes to listings**  **7 Resubmissions**  **8 Pricing Matters**  **9 Matters relating to PBS review**  **10 Subcommittee and Working Party reports**  **11 Other business**  **12 Correspondence**  **13 Further information**  **14 Late papers**  **15 Tabled papers**  Consumers will have the opportunity to provide comments on new drug submissions (item 5), changes to listings (item 6) and resubmissions (item 7). In many circumstances, consumers will be able to comment on items in other sections of the agenda. The submissions for which input is sought will be listed in alphabetical order by drug name. There is no provision for consumer comments to the PBAC on agenda item 8 which relates to pricing matters.  Pharmaceutical benefits listed in the Schedule fall into three broad categories:  *Unrestricted benefits* – have no restrictions on their therapeutic uses;  *Restricted benefits* – can only be prescribed for specific therapeutic uses (noted as Restricted benefit); and  *Authority required benefits* – Authority required benefits fall into two categories:   * *Authority required benefits* require prior approval from Services Australia or the DVA (noted as Authority required) * *Authority required (STREAMLINED) benefits* do not require prior approval from Services Australia or the DVA but require the recording of a streamlined authority code (noted as Authority required (STREAMLINED)).   Initial submissions are categorised broadly as:   * *Category 1 or 2:* Submissions to list new medicines on the Schedule of Pharmaceutical Benefits or to make substantial changes to current listings are generally classified as Category 1 or 2 submissions. These submissions require presentation of an economic evaluation. * *Category 3 or 4:* Submissions that relate to new forms of previously listed products and changes to the conditions of use e.g. change in maximum quantity/repeats or clarifying the wording of a restriction (while not altering the intended use) are considered to be Category 3 or 4 submissions. These submissions do not usually require the presentation of an economic evaluation.   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 PBS listing) | Breast cancer | Resubmission to request a General Schedule Authority Required (telephone/online) listing for use in combination with standard adjuvant endocrine therapy for the treatment of hormone receptor positive (HR+), human epidermal growth factor receptor 2 negative (HER2-), lymph node-positive, invasive, resected early breast cancer at high risk of disease recurrence. |
| ACALABRUTINIB  Capsule 100 mg  Calquence®  AstraZeneca Pty Ltd  (Other matters) | Relapsed or refractory chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL). | To request the PBAC consider the previously estimated utilisation for relapsed or refractory CLL or SLL. |
| ALIROCUMAB   Injection 300 mg in 2 mL single dose autoinjector   Praluent®  Sanofi-Aventis Australia Pty Ltd  (New PBS listing) | Familial heterozygous hypercholesterolaemia and non-familial hypercholesterolaemia. | To request listing of a new form and strength under the same conditions as the currently listed form and strengths of alirocumab for the treatment of familial heterozygous hypercholesterolaemia and non-familial hypercholesterolaemia. |
| AMINO ACID FORMULA WITH VITAMINS AND MINERALS, WITHOUT METHIONINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID   Sachets containing oral powder 12.5 g, 30 (HCU Explore5)  HCU Explore5  Vitaflo Australia Pty Limited   (New PBS listing) | Pyridoxine non-responsive homocystinuria (HCU) | To request a General Schedule Restricted Benefit listing for the dietary management of HCU. |
| AMINO ACID FORMULA WITH VITAMINS AND MINERALS, WITHOUT PHENYLALANINE AND TYROSINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID   Sachets containing oral powder 12.5 g, 30 (TYR Explore5)  TYR Explore5  Vitaflo Australia Pty Limited  (New PBS listing) | Tyrosinaemia | To request a General Schedule Restricted Benefit listing for the dietary management of tyrosinaemia. |
| AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE AND ISOLEUCINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID  Sachets containing oral powder 12.5 g, 30 (MSUD Explore5)  MSUD Explore5  Vitaflo Australia Pty Limited   (New PBS listing) | Maple syrup urine disease (MSUD) | To request a General Schedule Restricted Benefit listing for the dietary management of patients with MSUD. |
| AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS  Oral powder 400 g (EleCare LCP)  EleCare® LCP  Abbott Australasia Pty Ltd  (Change to PBS listing) | Cows' milk protein enteropathy  Severe cows' milk protein  enteropathy with failure to thrive  Combined intolerance to cows'  milk protein, soy protein and  protein hydrolysate formulae  Cows' milk anaphylaxis  Proven combined immunoglobulin  E (IgE) mediated allergy to cows'  milk protein and soy protein  Severe intestinal malabsorption  including short bowel syndrome | To request that EleCare LCP with new source of docosahexaenoic acid (DHA) continue to be listed on the PBS under the current conditions. |
| ANIFROLUMAB  Solution concentrate for I.V. infusion 300 mg in 2 mL vial  Saphnelo®  AstraZeneca Pty Ltd  (New PBS listing) | Systemic lupus erythematosus (SLE) | Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (written) listing for the treatment of severe SLE with a high degree of disease activity despite standard therapy. |
| APREMILAST  Tablet 30 mg Pack containing 4 tablets of 10 mg, 4 tablets of 20 mg and 19 tablets of 30 mg   Otezla®  Amgen Australia Pty Limited  (Change to PBS listing) | Psoriatic arthritis (PsA) | To request a General schedule Authority Required (STREAMLINED) listing for the treatment of severe active PsA. |
| BIMEKIZUMAB  Injection 160 mg in 1 mL single use pre-filled syringe Injection 160 mg in 1 mL single use pre-filled pen   Bimzelx®  UCB Australia Proprietary Limited  (New PBS listing) | Chronic plaque psoriasis | To request a General Schedule Authority Required (written) listing for the treatment of chronic plaque psoriasis. |
| BUDESONIDE  Tablet 500 micrograms (orally disintegrating)  Tablet 1 mg (orally disintegrating)  Jorveza®  Dr Falk Pharma Australia Pty Ltd  (Change to PBS listing) | Eosinophilic oesophagitis (EoE) | To request PBAC advice regarding the number of biopsies to confirm eligibility for initial treatment; removal of the histological assessment to determine eligibility for continuing treatment; and an expansion to the treatment criteria to include physicians or surgeons experienced in the diagnosis and management of EoE. |
| CARMELLOSE WITH GLYCERIN AND WITH HYALURONIC ACID  Eye drops containing carmellose sodium 5 mg with glycerin 9 mg and with hyaluronic acid 1 mg per mL, 10 mL  Optive Fusion®  Allergan Australia Pty Limited  (New PBS listing) | Severe dry eye syndrome | To request a General Schedule Restricted Benefit listing for the treatment of severe dry eye syndrome. |
| CHLORMETHINE HYDROCHLORIDE  0.016% (160 microgram/g) gel  Ledaga®  Juniper Biologics Pty Ltd  (New PBS listing) | Mycosis fungoides-type cutanous T-cell lymphoma (MF-type CTCL) | To request a General Schedule Authority Required (telephone/electronic) listing for the treatment of adults with MF-type CTCL. |
| DARATUMUMAB  Solution for I.V. infusion 100 mg in 5 mL vial Solution for I.V. infusion 400 mg in 20 mL vial Solution for S.C. injection 1,800 mg in 15 mL vial  Darzalex®  Janssen-Cilag Pty Ltd  (Change to PBS listing) | Multiple myeloma | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (telephone/online) listing for the I.V. and S.C. formulations and a General Schedule Authority Required (telephone/online) listing for the S.C. formulation for use in combination with lenalidomide and dexamethasone for the treatment of transplant ineligible, newly diagnosed multiple myeloma. |
| DIFELIKEFALIN  Solution for I.V. injection 50 mcg in 1 mL vial  Korsuva®  Vifor Pharma Pty Limited  (New PBS listing) | Chronic kidney disease associated pruritus | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (telephone/online) listing for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in adult patients on haemodialysis. |
| DURVALUMAB  Solution concentrate for I.V. infusion 120 mg in 2.4 mL vial Solution concentrate for I.V. infusion 500 mg in 10 mL vial  Imfinzi®  AstraZeneca Pty Ltd  (Change to PBS listing) | Biliary tract cancer | To request a Section 100 (Efficient Funding of Chemotherapy program) Authority Required (STREAMLINED) listing for the treatment of advanced biliary tract cancer. |
| ENZALUTAMIDE  Capsule 40 mg  Xtandi®  Astellas Pharma Australia Pty Ltd  (Change to PBS listing) | Prostate cancer | To request a General Schedule Authority Required (telephone/online) listing for the treatment of metastatic hormone-sensitive prostate cancer in patients with low volume disease, and in high volume disease where the patient is unsuitable for docetaxel due to poor ECOG status, comorbidities, or contraindications. |
| FINERENONE  Tablet 10 mg Tablet 20 mg  Kerendia®   Bayer Australia Ltd  (New PBS listing) | Chronic kidney disease in Type 2 diabetes | Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of chronic kidney disease in patients with type 2 diabetes mellitus. |
| FOSNETUPITANT (AS CHLORIDE HYDROCHLORIDE)/PALONOSETRON (AS HYDROCHLORIDE)   Solution concentrate for I.V. infusion containing fosnetupitant 235 mg and palonosetron 0.25 mg in 20 mL vial  Akynzeo®IV  Juniper Biologics Pty Ltd  (New PBS listing) | Nausea and vomiting | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) and a General Schedule Authority Required (STREAMLINED) listing for the treatment of nausea and vomiting in patients receiving highly, or moderately, emetogenic chemotherapy. |
| GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS  Oral liquid 250 mL, 30 (Tylactin RTD)  Tylactin® RTD  Cortex Health Pty Ltd  (Other matters) | Tyrosinaemia | To request Tylactin RTD with new formulation continue to be listed on the PBS under the existing conditions. |
| GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS  Sachets containing oral powder 40 g, 30 (Camino Pro Bettermilk)  Oral liquid 250 mL, 30 (PKU Glytactin RTD 15)  Camino Pro® Bettermilk PKU Glytactin RTD 15  Cortex Health Pty Ltd  (New PBS listing) | Phenylketonuria | To request Camino Pro Bettermilk and PKU Glytactin RTD 15 with new formulation continue to be listed on the PBS under the existing conditions. The submission also requested a new pack size for Camino Pro Bettermilk of 30 x 40 g sachets. |
| HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE  Oral liquid 250 mL, 30 (KetoVie 3:1) Oral liquid 250 mL, 30 (KetoVie 4:1) Oral liquid 250 mL, 30 (KetoVie Peptide 4:1)  KetoVie® 3:1  KetoVie® 4:1  KetoVie® Peptide 4:1  Cortex Health Pty Ltd  (Other matters) | Ketogenic diet | To request KetoVie 3:1, KetoVie 4:1, and KetoVie Peptide 4:1 with new formulation continue to be listed on the PBS under the existing conditions. |
| HYALURONIC ACID WITH POLYETHYLENE GLYCOL 400 WITH PROPYLENE GLYCOL WITH HYDROXYPROPYL GUAR  Eye drops containing sodium hyaluronate 1.5 mg per mL with polyethylene glycol 400, propylene glycol and hydroxypropyl guar, 10 mL  Systane® Hydration  Alcon Laboratories (Australia) Pty Ltd   (New PBS listing) | Severe dry eye syndrome | To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops. |
| INCLISIRAN  Injection 284 mg in 1.5 mg single use pre-filled syringe  Leqvio®  Novartis Pharmaceuticals Australia Pty Limited  (New PBS listing) | Hypercholesterolaemia | To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of hypercholesterolaemia and atherosclerotic cardiovascular disease. |
| LAROTRECTINIB  Oral solution 20 mg per mL, 50 mL, 2  Vitrakvi®  Bayer Australia Ltd  (New PBS listing)  WITHDRAWN | Solid tumours harbouring  neurotrophic receptor tyrosine  kinase (NTRK) gene fusions | To request listing a new form and formulation of oral solution under the existing conditions to replace the currently listed oral solution of larotrectinib. |
| MIFEPRISTONE AND MISOPROSTOL  Pack containing 1 tablet mifepristone 200 mg and 4 tablets misoprostol 200 micrograms  MS-2 Step®  MS Health Pty Ltd  (Change to PBS listing) | Termination of an intrauterine pregnancy | To request a change to the restriction level of the existing listing from Authority Required to Authority Required (STREAMLINED) for termination of an intrauterine pregnancy. |
| NATALIZUMAB  Injection 150 mg in 1 mL single dose pre-filled syringe  Tysabri®  Biogen Australia Pty Ltd  (New PBS listing) | Relapsing-remitting multiple sclerosis (RRMS) | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing of a new form of natalizumab for the treatment of RRMS. |
| NETUPITANT WITH PALONOSETRON  Capsule containing netupitant 300 mg with palonosetron 500 microgram (as hydrochloride)  Akynzeo®  Juniper Biologics Pty Ltd  (Change to PBS listing) | Nausea and vomiting | To request a change to the clinical criteria to align restrictions with the National Comprehensive Cancer Network Guidelines for the treatment of nausea and vomiting. |
| NIRAPARIB  Capsule 100 mg  Zejula®  GlaxoSmithKline Australia Pty Ltd  (Change to PBS listing) | Epithelial ovarian, fallopian tube, or primary peritoneal cancer | To request an expanded General Schedule Authority Required (telephone/online) listing for the treatment of newly diagnosed, homologous recombination deficiency (HRD) positive, BRCA wild type advanced (FIGO Stage III-IV) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer. |
| 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   (Other matters) | Gastro-oesophageal cancers | To request that first-line oesophageal squamous cell carcinoma (OSCC) patients are included in the financial estimates for the treatment of advanced or metastatic gastro-oesophageal cancers. |
| 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-small cell lung cancer (NSCLC) | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the neoadjuvant treatment of resectable NSCLC. |
| OLAPARIB  Tablet 100 mg Tablet 150 mg  Lynparza®  AstraZeneca Pty Ltd  (New PBS listing) | Breast cancer | To request a General Schedule Authority Required (telephone/online) listing for the treatment of human epidermal growth factor 2 (HER2)-negative high risk early breast cancer with a confirmed germline BRCA1 or BRCA2 mutation who have previously been treated with neoadjuvant or adjuvant chemotherapy. |
| OSILODROSTAT  Tablet 1 mg Tablet 5 mg Tablet 10 mg  Isturisa®  Recordati Rare Diseases Australia Pty. Ltd.  (New PBS listing) | Cushing syndrome | To request a General Schedule Authority Required (telephone/online) listing for the treatment of adult patients with endogenous Cushing syndrome who are not candidates for surgery or for whom surgery was not curative. |
| PATIROMER  Sachet, 8.4 g powder for oral liquid  Sachet, 16.8 g powder for oral liquid  Veltassa®  Vifor Pharma Pty Limited  (New PBS listing) | Hyperkalaemia | Resubmission to request a General Schedule Authority Required listing for the treatment of chronic hyperkalaemia in patients with stage 3 or stage 4 chronic kidney disease. |
| PEMBROLIZUMAB  Solution concentrate for I.V. infusion 100 mg in 4 mL vial  Keytruda®  Merck Sharp & Dohme (Australia) Pty Ltd  (Change to PBS listing) | Breast cancer | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of locally recurrent unresectable or metastatic triple negative breast cancer. |
| PEMBROLIZUMAB  Solution concentrate for I.V. infusion 100 mg in 4 mL vial  Keytruda®  Merck Sharp & Dohme (Australia) Pty Ltd  (Change to PBS listing) | Breast cancer | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of early stage triple negative breast cancer in patients who have not received prior systemic therapy. |
| PEMETREXED   Solution concentrate for I.V. infusion 100 mg in 4 mL vial Solution concentrate for I.V. infusion 500 mg in 20 mL vial Solution concentrate for I.V. infusion 1000 mg in 40 mL vial  Pemetrexed EVER Pharma  Interpharma Pty Ltd  (New PBS listing) | Mesothelioma  Locally advanced or metastatic non-small cell lung cancer | To request listing a new form of pemetrexed under the existing conditions as the currently listed pemetrexed powder for I.V. infusion. |
| PNEUMOCOCCAL CONJUGATE VACCINE, 15 VALENT ADSORBED  0.5 mL pre-filled syringe  Vaxneuvance®  Merck Sharp & Dohme (Australia) Pty Ltd  (New PBS listing) | Prevention of pneumococcal disease | To request a National Immunisation Program listing for the prevention of pneumococcal disease in paediatrics. |
| RAVULIZUMAB  Solution concentrate for I.V. infusion 300 mg in 3 mL vial Solution concentrate for I.V. infusion 1.1 g in 11 mL vial  Ultomiris®  Alexion Pharmaceuticals Australasia Pty Ltd  (Change to PBS listing) | Atypical haemolytic uraemic syndrome (aHUS) | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (written) listing for the treatment of aHUS. |
| RELATLIMAB AND NIVOLUMAB  Solution concentrate for I.V. infusion containing 80 mg relatlimab and 240 mg nivolumab in 20 mL vial  Opdualag®  Bristol-Myers Squibb Australia Pty Ltd  (New PBS listing) | Melanoma | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of unresectable Stage III or Stage IV malignant melanoma. |
| RIOCIGUAT   500 microgram tablet, 84 1 mg tablet, 84 1.5 mg tablet, 84 2 mg tablet, 84 2.5 mg tablet, 84  Adempas®  Bayer Australia Ltd  (Change to PBS listing)  WITHDRAWN | Pulmonary arterial hypertension Chronic thromboembolic pulmonary hypertension | To request a change in pack size from a pack of 84 tablets to a pack of 42 tablets and an increase of maximum quantity and number of repeats for the existing listings of 0.5 mg, 1 mg, 1.5 mg, and 2 mg. The submission also requests an increase to the maximum number of repeats for the existing listings of 2.5 mg (84 pack size). |
| RISDIPLAM  Powder for oral solution 0.75 mg per 1 mL, 80 mL  Evrysdi®  Roche Products Pty Ltd  (Change to PBS listing) | Spinal muscular atrophy (SMA) | Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (written) listing for the treatment of   1. adults diagnosed with 5q SMA with symptom onset prior to 19 years of age,   (ii) patients with confirmed genetic diagnosis of SMA (SMA1 deletion or mutation) who have a SMN2 gene copy number of 1 or 2, and  (iii) patients with confirmed genetic diagnosis of SMA (SMA1 deletion or mutation) who have a SMN2 gene copy number of 3. |
| RISPERIDONE  Powder for I.M. injection 75 mg (modified release) with 0.383 mL diluent in pre-filled syringe Powder for I.M. injection 100 mg (modified release) with 0.49 mL diluent in pre-filled syringe   Okedi®  Maxx Pharma Pty Ltd  (New PBS listing)  To be considered at a future PBAC meeting | Schizophrenia | To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of schizophrenia. |
| ROMOSOZUMAB  Injection 105 mg in 1.17 mL single use pre-filled syringe  Evenity®  Amgen Australia Pty Limited  (Change to PBS listing) | Osteoporosis | Resubmission to request a General Schedule Authority Required (Telephone/electronic) listing for the treatment of severe established osteoporosis. |
| TEBENTAFUSP  Solution concentrate for I.V. infusion 100 mcg in 0.5 mL vial  Kimmtrak®  Synevi Pty Limited  (New PBS listing) | Advanced (unresectable or metastatic) human leukocyte antigen (HLA)-A\*02:01-positive uveal melanoma | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (telephone/online) listing for the treatment of HLA-A\*02:01-positive adult patients with advanced (unresectable or metastatic) uveal melanoma. |
| TICAGRELOR   Tablet, 90 mg  Brilinta®  AstraZeneca Pty Ltd  (Change to PBS listing) | Acute coronary syndrome | To request a change to the restriction level of the existing listing from Authority Required (STREAMLINED) to an unrestricted benefit. |
| TILDRAKIZUMAB  Injection 100 mg in 1 mL single use pre-filled syringe  Ilumya®  Sun Pharma ANZ Pty Ltd  (Change to PBS listing) | Severe chronic plaque psoriasis | To request adding a grandfathering restriction to allow eligible patients enrolled in two tildrakizumab clinical trials to transition to PBS-subsidised tildrakizumab after completing the clinical trials. |
| TOFACITINIB  Tablet 5 mg  Xeljanz®  Pfizer Australia Pty Ltd  (Change to PBS listing) | Ankylosing spondylitis | To request a General Schedule Authority Required (written) listing for the treatment of ankylosing spondylitis. |
| TOFACITINIB  Tablet 5 mg Oral liquid 1 mg per mL, 240 mL  Xeljanz®  Pfizer Australia Pty Ltd  (New PBS listing) | Juvenile idiopathic arthritis | To request a General Schedule Authority Required (written) listing for the treatment of severe active juvenile idiopathic arthritis. |
| ELEXACAFTOR WITH TEZACAFTOR AND WITH IVACAFTOR, AND IVACAFTOR  Pack containing 56 tablets elexacaftor 100 mg with tezacaftor 50 mg and with ivacaftor 75 mg and 28 tablets ivacaftor 150 mg  Pack containing 56 tablets elexacaftor 50 mg with tezacaftor 25 mg and with ivacaftor 37.5 mg and 28 tablets ivacaftor 75 mg  Trikafta®  VERTEX PHARMACEUTICALS (AUSTRALIA) PTY. LTD.  (New PBS listing) | Cystic fibrosis | To request reconsideration of the financial estimates for Trikafta for the treatment of cystic fibrosis in patients who are aged 6 to 11 years and who have at least one F508del mutation on the cystic fibrosis transmembrane conductance regulator (CFTR) gene. |
| UPADACITINIB   Tablet 15 mg Tablet 30 mg Tablet 45 mg  Rinvoq®  Abbvie Pty Ltd  (Change to PBS listing)  To be considered at a future PBAC meeting | Crohn disease | To request a General Schedule Authority Required (written) listing for the treatment of severe Crohn disease. |
| URSODEOXYCHOLIC ACID   Capsule 250 mg Tablet 500 mg  Ursofalk®  Dr Falk Pharma Australia Pty Ltd  (Change to PBS listing) | Primary biliary cholangitis | To request an increase to the number of repeats for the treatment of primary biliary cholangitis. |
| VARICELLA ZOSTER VIRUS RECOMBINANT VACCINE  Injection [1 vial] & adjuvant substance diluent [0.5 mL vial]   Shingrix®  GlaxoSmithKline Australia Pty Ltd  (New PBS listing) | Prevention of herpes zoster and post-herpetic neuralgia | Resubmission to request a National Immunisation Program listing for the prevention of herpes zoster and post-herpetic neuralgia in:  • adults 65 years of age with ongoing catch-up for adults over 65 years of age.  • Aboriginal and Torres Strait Islander adults 50 years of age with ongoing catch-up for adults over 50 years of age. |
| ZANUBRUTINIB  Capsule 80 mg  Brukinsa®  Beigene Aus Pty Ltd  (Change to PBS listing) | Chronic lymphocytic leukaemia (CLL)/Small lymphocytic leukaemia (SLL) | To request a General Schedule Authority Required (Telephone/Streamlined) listing for the treatment of treatment naive CLL/SLL. |
| ZANUBRUTINIB  Capsule 80 mg  Brukinsa®  Beigene Aus Pty Ltd  (Change to PBS listing) | Chronic lymphocytic leukaemia (CLL)/Small lymphocytic leukaemia (SLL) | To request a General Schedule Authority Required (Telephone/Streamlined) listing for the treatment of relapsed or refractory CLL/SLL considered unsuitable for treatment or retreatment with a purine analogue. |
| ARIPIPRAZOLE  Powder for injection 400 mg (as monohydrate) with diluent pre-filled dual chamber syringe  Abilify Maintena®  Lundbeck Australia Pty Ltd  (Review of positive PBAC recommendations not accepted by applicants) | Schizophrenia |  |
| AVELUMAB  Solution concentrate for I.V. infusion 200 mg in 10 mL  Bavencio®  Merck Healthcare Pty Ltd  (Review of positive PBAC recommendations not accepted by applicants) | Stage IV clear cell variant renal cell carcinoma |  |
| IBRUTINIB  Capsule 140 mg  Imbruvica®  Janssen-Cilag Pty Ltd  (Review of positive PBAC recommendations not accepted by applicants) | Chronic lymphocytic leukaemia (CLL)/ Small lymphocytic leukaemia (SLL) |  |
| MENINGOCOCCAL POLYSACCHARIDE SEROGROUPS A, C, W-135 AND Y CONJUGATE VACCINE  Injection 0.5 mL  MenQuadfi®  Sanofi-Aventis Australia Pty Ltd  (Review of positive PBAC recommendations not accepted by applicants) | Prevention of meningococcal disease |  |
| PANCREATIC EXTRACT  Capsule (containing enteric coated minimicrospheres) providing not less than 20,000 BP units of lipase activity   Creon®  Mylan Health Pty Ltd  (Review of positive PBAC recommendations not accepted by applicants) | Cystic fibrosis and unrestricted benefit |  |
| EVOLOCUMAB  All strengths  Repatha®  Amgen Australia Pty Ltd  (Sub-committee report  DUSC Analysis) | Hypercholesterolaemia | To compare utilisation of evolocumab across all listed indications. |
| IMPACT OF REGULATORY REFORMS ON UTILISATION OF OPIOIDS  All brands and strengths  Various sponsors  (Sub-committee report DUSC Analysis) | Opioid medications for the relief of pain | To examine the impact of the 1 June 2020 regulatory reforms and associated PBS listing changes for opioid analgesics. |

Version 4

Items added or amended

1. HYALURONIC ACID WITH POLYETHYLENE GLYCOL 400 WITH PROPYLENE GLYCOL WITH HYDROXYPROPYL GUAR (Systane® Hydration) – drug name and form for item amended
2. UPADACITINIB (Rinvoq®) – to be considered at a future PBAC meeting
3. RISPERIDONE (Okedi®) – to be considered at a future PBAC meeting
4. ELEXACAFTOR WITH TEZACAFTOR AND WITH IVACAFTOR, AND IVACAFTOR (Trikafta®) – added

Items added or amended previously

1. AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS (EleCare® LCP) – drug use for item amended
2. NIRAPARIB (Zejula®) – purpose of submission for item amended
3. NIVOLUMAB (Opdivo®) for NSCLC – form for item amended
4. VARICELLA ZOSTER VIRUS RECOMBINANT VACCINE (Shingrix®) – purpose of submission for item amended
5. Addition of ARIPIPRAZOLE (Abilify Maintena®), AVELUMAB (Bavencio®), IBRUTINIB (Imbruvica®), MENINGOCOCCAL POLYSACCHARIDE SEROGROUPS A, C, W-135 AND Y CONJUGATE VACCINE (MenQuadfi®) and PANCREATIC EXTRACT (Creon®) – review of PBAC recommendations not accepted by applicants
6. Sub-committee report (DUSC Analysis): EVOLOCUMAB (Repatha®) – added
7. Sub-committee report (DUSC Analysis): IMPACT OF REGULATORY REFORMS ON UTILISATION OF OPIOIDS – added
8. PATIROMER (Veltassa®) – added
9. BIMEKIZUMAB (Bimzelx®) – form for item amended
10. FOSNETUPITANT (AS CHLORIDE HYDROCHLORIDE)/PALONOSETRON (AS HYDROCHLORIDE) (Akynzeo®IV) – strength for item amended
11. GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS (Camino Pro® Bettermilk, PKU Glytactin RTD 15) – form and purpose of submission for item amended
12. LAROTRECTINIB (Vitrakvi®) – withdrawn
13. RIOCIGUAT (Adempas®) – withdrawn
14. RISPERIDONE (Okedi®) – form for item amended