**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA**
**JULY 2018 PBAC MEETING**

**Closing date for consumer comments 6 June 2018**

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 Medicare Australia or the DVA (noted as Authority required)
- *Authority required (STREAMLINED) benefits* do not require prior approval from Medicare Australia or the DVA but require the recording of a streamlined authority code (noted as Authority required (STREAMLINED)).

Submissions are categorised broadly as major or minor:

- *Major:* Submissions to list new medicines on the Schedule of Pharmaceutical Benefits or to make substantial changes to current listings are generally classified as major submissions. Major submissions require presentation of an economic evaluation.
- *Minor:* Submissions that relate to new forms of previously listed products and changes to the conditions of use e.g. change in maximum quantity/repeats or clarifying the wording of a restriction (while not altering the intended use) are considered to be minor submissions. Minor submissions do not usually require the presentation of an economic evaluation.

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|---|---|---|---|
| New listing<br><br>(Minor Submission) | ADALIMUMAB<br><br>Injection 20 mg in 0.2 mL pre-filled syringe<br>Injection 80 mg in 0.8 mL pre-filled pen<br><br>Humira®<br><br>AbbVie Pty Ltd | Severe active rheumatoid arthritis;<br>Severe psoriatic arthritis;<br>Ankylosing spondylitis;<br>Severe chronic plaque psoriasis;<br>Severe active juvenile idiopathic arthritis;<br>Severe Crohn disease;<br>Refractory fistulating Crohn disease;<br>Moderate to severe ulcerative colitis;<br>Moderate to severe hidradenitis suppurativa | To request an Authority Required listing for two new forms of adalimumab and to request the current Section 100 (Highly Specialised Drug) listings for juvenile idiopathic arthritis (JIA) be changed to a General Schedule listing. |
| New listing<br><br>(Minor Submission) | ADALIMUMAB<br><br>Injection 20 mg in 0.4 mL pre-filled syringe<br>Injection 40 mg in 0.8 mL pre-filled syringe<br>Injection 40 mg in 0.8 mL pre-filled pen<br><br>Amgevita®<br><br>Amgen Australia Pty Limited | Severe active rheumatoid arthritis;<br>Severe psoriatic arthritis;<br>Ankylosing spondylitis;<br>Severe chronic plaque psoriasis;<br>Severe active juvenile idiopathic arthritis;<br>Severe Crohn disease;<br>Refractory fistulating Crohn disease;<br>Moderate to severe ulcerative colitis;<br>Moderate to severe hidradenitis suppurativa | To request an Authority Required listing of this biosimilar brand for all indications for which the reference biological is currently PBS listed. |
| New listing<br><br>(Minor Submission) | ADALIMUMAB<br><br>Injection 40 mg in 0.8 mL pre-filled syringe<br>Injection 40 mg in 0.8 mL single dose autoinjector<br><br>Hadlima®<br><br>Merck Sharp & Dohme (Australia) Pty Ltd | Severe active rheumatoid arthritis (RA) | To request an Authority Required listing of this biosimilar brand for the rheumatoid arthritis indication for which the reference biological is currently listed. |

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| New listing<br><br>(Minor Submission) | APOMORPHINE<br><br>Injections, cartridges, 30 mg in 3 mL<br><br>Apomine® Intermittent<br><br>Pfizer Australia Pty Ltd | Parkinson disease | To request a Section 100 (Highly Specialised Drug) listing of a new form of apomorphine. |
| New listing<br><br>(Minor Submission) | ARIPIPRAZOLE<br><br>Powder for injection 400 mg (as monohydrate) with diluent, pre-filled syringe<br><br>Abilify Maintena®<br><br>Lundbeck Australia Pty Ltd | Schizophrenia | To request an Authority Required (STREAMLINED) benefit for a new form of the long acting aripiprazole. |
| New listing<br><br>(Major Submission) | AVELUMAB<br><br>Solution concentrate for I.V. infusion 200 mg in 10 mL<br><br>Bavencio®<br><br>Merck Serono Australia Pty Ltd (with Pfizer Australia Pty Ltd) | Metastatic merkel cell carcinoma (MCC) | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of patients with metastatic merkel cell carcinoma (MCC). |
| New listing<br><br>(Major Submission) | BEZLOTOXUMAB<br><br>Solution concentrate for I.V. infusion 1000 mg in 40 mL<br><br>Zinplava®<br><br>Merck Sharp & Dohme (Australia) Pty Ltd | Prevention of recurrent clostridium difficile infection (rCDI) | Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for prevention of recurrent clostridium difficile infection (rCDI) in patients receiving antibiotic treatment, who are at high risk of recurrence. |

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| Change to listing<br><br>(Major Submission) | BLINATUMOMAB<br><br>Powder for I.V. infusion 38.5 micrograms<br><br>Blincyto®<br><br>Amgen Australia Pty Ltd | Acute lymphoblastic leukaemia (ALL) | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of B-Cell precursor ALL in patients in haematological complete remission with minimal residual disease following induction chemotherapy. |
| Change to recommended listing<br><br>(Major Submission) | BRENTUXIMAB VEDOTIN<br><br>Powder for I.V. infusion 50 mg<br><br>Adcetris®<br><br>Takeda Pharmaceuticals Australia Pty Ltd | Refractory or relapsed CD30 positive cutaneous T-cell lymphomas (CTCL) | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of refractory or relapsed CD30 positive cutaneous T-cell lymphomas (CTCL). |
| New listing<br><br>(Minor Submission) | BUDESONIDE<br><br>Capsule (modified release) 3 mg<br><br>Entocort®<br><br>Emerge Health Pty Ltd | Mild to moderate Crohn disease | Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of patients with mild to moderate Crohn disease. |

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| New listing<br><br>(Minor Submission) | CARMELLOSE<br>HYPROMELLOSE<br><br>Eye drops containing carmellose sodium 5 mg per mL, 10 mL<br>Eye drops containing hypromellose 3 mg per mL, 10 mL<br><br>Evolve® carmellose<br>Evolve® hypromellose<br><br>Contact Lens Centre Australia | Severe dry eye syndrome | To request an Authority Required (STREAMLINED) listing for the treatment of severe dry eye syndrome. |
| New listing<br><br>(Major Submission) | CERLIPONASE ALFA<br><br>Solution for infusion 150 mg with flushing solution<br><br>Brineura®<br><br>BioMarin Pharmaceutical Australia Pty Ltd | Neuronal ceroid lipofuscinosis type 2 (CLN2) disease (also known as tripeptidyl peptidase 1 deficiency) | To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of neuronal ceroid lipofuscinosis type 2 (CLN2) disease. |
| New listing<br><br>(Minor Submission) | CLADRIBINE<br><br>Tablet 10 mg<br><br>Mavenclad®<br><br>Merck Serono Australia Pty Ltd | Relapsing remitting multiple sclerosis (RRMS) | Resubmission to request an Authority Required listing for the treatment of relapsing remitting multiple sclerosis (RRMS). |

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| Change to listing<br><br>(Minor Submission) | CRIZOTINIB<br><br>Capsule 200 mg<br>Capsule 250 mg<br><br>Xalkori®<br><br>Pfizer Australia Pty Ltd | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) with a ROS1 gene rearrangement confirmed by fluorescent in situ hybridisation (FISH) testing | Resubmission to request an Authority Required listing for the treatment of patients with Stage IIIB (locally advanced) or Stage IV (metastatic) NSCLC with a ROS1 gene rearrangement confirmed by FISH testing, in patients who have failed at least one treatment with platinum based chemotherapy. |
| New listing<br><br>(Minor Submission) | DEFERASIROX<br><br>Tablet 90 mg<br>Tablet 180 mg<br>Tablet 360 mg<br><br>Jadenu®<br><br>Novartis Pharmaceuticals Australia Pty Ltd | Chronic iron overload | To request Section 100 (Highly Specialised Drug) listings of a new form of deferasirox. |
| Change to listing<br><br>(Major Submission) | DENOSUMAB<br><br>Injection 120 mg in 1.7 mL<br><br>Xgeva®<br><br>Amgen Australia Pty Ltd | Multiple myeloma (MM) | To request an Authority Required (STREAMLINED) listing for the treatment of multiple myeloma (MM). |
| New listing<br><br>(Major Submission) | DOLUTEGRAVIR WITH RILPIVIRINE<br><br>Tablet containing dolutegravir 50 mg with rilpivirine 25 mg<br><br>Juluca®<br><br>ViiV Healthcare Pty Ltd | Human immunodeficiency virus (HIV) infection | To request a Section 100 (Highly Specialised Drugs Program - Community Access) Authority Required (STREAMLINED) listing for the treatment of patients with HIV infection. |

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| New listing<br><br>(Major Submission) | DUPILUMAB<br><br>Injection 300 mg in 2 mL single dose pre-filled syringe<br><br>Dupixent®<br><br>Sanofi-aventis Australia Pty Ltd | Severe atopic dermatitis | To request an Authority Required listing for the treatment of patients with severe atopic dermatitis who have had an inadequate response, intolerance or contraindication to treatment with cyclosporin. |
| New listing<br><br>(Major Submission) | ERENUMAB<br><br>Injection 70 mg in 1 mL single dose pre-filled pen<br><br>Aimovig®<br><br>Novartis Pharmaceuticals Australia Pty Ltd | Chronic migraine | To request an Authority Required (STREAMLINED) listing for prophylaxis in patients with chronic migraine who meet certain conditions |
| Change to recommended listing<br><br>(Major Submission) | 1) ERTUGLIFLOZIN WITH SITAGLIPTIN<br>2) ERTUGLIFLOZIN<br>3) ERTUGLIFLOZIN WITH METFORMIN<br>4) SITAGLIPTIN<br>5) SITAGLIPTIN WITH METFORMIN<br><br>1) Tablet containing 5 mg ertugliflozin with 100 mg sitagliptin (as phosphate monohydrate);<br>Tablet containing 15 mg ertugliflozin with 100 mg sitagliptin (as phosphate monohydrate)<br>2) Ertugliflozin Tablet 5 mg;<br>Ertugliflozin Tablet 15 mg<br>3) Tablet containing 2.5 mg ertugliflozin with 500 mg metformin hydrochloride; | Type 2 diabetes mellitus (T2DM) | To request an Authority Required (STREAMLINED) listing for triple oral combination therapy of ertugliflozin and sitagliptin with metformin for the treatment of patients with type 2 diabetes mellitus (T2DM). |

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| | Tablet containing 2.5 mg ertugliflozin with 1 g metformin hydrochloride;<br>Tablet containing 7.5 mg ertugliflozin with 500 mg metformin hydrochloride;<br>Tablet containing 7.5 mg ertugliflozin with 1 g metformin hydrochloride<br>4) Sitagliptin Tablet 25 mg (as phosphate monohydrate);<br>Sitagliptin Tablet 50 mg (as phosphate monohydrate);<br>Sitagliptin Tablet 100 mg (as phosphate monohydrate);<br>5) Tablet containing 50 mg sitagliptin (as phosphate monohydrate) with 500 mg metformin hydrochloride;<br>Tablet containing 50 mg sitagliptin (as phosphate monohydrate) with 850 mg metformin hydrochloride;<br>Tablet containing 50 mg sitagliptin (as phosphate monohydrate) with 1000 mg metformin hydrochloride;<br>Tablet (modified release) containing 50 mg sitagliptin (as phosphate monohydrate) with 1000 mg metformin hydrochloride;<br>Tablet (modified release) containing 100 mg sitagliptin (as phosphate monohydrate) with 1000 mg metformin hydrochloride<br><br>1) Steglujan®<br>2) Steglatro®<br>3) Segluromet®<br>4) Januvia® | | |

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| | 5) Janumet®; Janumet XR®<br><br>Merck Sharp & Dohme (Australia) Pty Ltd | | |
| New listing<br><br>(Minor Submission) | 1) ERTUGLIFLOZIN<br>2) ERTUGLIFLOZIN with METFORMIN<br><br>1) Tablet containing 15 mg ertugliflozin<br>2) Tablet containing 7.5 mg ertugliflozin with 500 mg metformin hydrochloride; Tablet containing 7.5 mg ertugliflozin with 1 g metformin hydrochloride<br><br>1) Steglatro®<br>2) Segluromet®<br><br>Merck Sharp & Dohme (Australia) Pty Limited | Type 2 diabetes mellitus (T2DM) | Resubmission to request an Authority Required (STREAMLINED) listing for higher strength formulations of ertugliflozin and ertugliflozin with metformin for dual oral combination therapy for patients with type 2 diabetes mellitus who are inadequately controlled with metformin or a sulfonylurea. |
| Change to listing<br><br>(Major Submission) | EVOLOCUMAB<br><br>Injection 140 mg in 1 mL single use pre-filled pen<br>Injection 420 mg in 3.5 mL single use pre-filled cartridge<br><br>Repatha®<br><br>Amgen Australia Pty Ltd | Hypercholesterolaemia with symptomatic atherosclerotic cardiovascular disease (ASCVD) who do not have underlying familial hypercholesterolaemia | Resubmission to request an Authority Required listing for treatment of patients with non-familial hypercholesterolaemia who have symptomatic atherosclerotic cardiovascular disease (ASCVD). |

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| New listing<br><br>(Major Submission) | FERRIC DERISOMALTOSE<br><br>Injection 500 mg (iron) in 5 mL<br><br>Monofer®<br><br>Pfizer Australia Pty Ltd | Iron deficiency anaemia | To request an unrestricted benefit listing. |
| Change to listing<br><br>(Major Submission) | GOLIMUMAB<br><br>Injection 50 mg in 0.5 mL single use pre-filled syringe<br>Injection 50 mg in 0.5 mL single use pre-filled pen<br><br>Simponi®<br>Simponi Smartject®<br><br>Janssen Cilag Pty Ltd | Active non-radiographic axial spondyloarthritis (nr-axSpA) | Resubmission to request an Authority Required listing for the treatment of active non-radiographic axial spondyloarthritis (nr-axSpA). |

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| Change to recommended listing<br><br>(Minor Submission) | GUANFACINE<br><br>Tablet containing guanfacine hydrochloride 1 mg<br>Tablet containing guanfacine hydrochloride 2 mg<br>Tablet containing guanfacine hydrochloride 3 mg<br>Tablet containing guanfacine hydrochloride 4 mg<br><br>Intuniv®<br><br>Shire Australia Pty Limited | Attention deficit hyperactivity disorder (ADHD) | Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of attention deficit hyperactivity disorder (ADHD) as add-on therapy in patients who have an inadequate response to stimulant therapy. |
| New listing<br><br>(Minor Submission) | GUSELKUMAB<br><br>Injection 100 mg in 1 mL single use pre-filled syringe<br><br>Tremfya®<br><br>Janssen-Cilag Pty Ltd | Severe chronic plaque psoriasis | Resubmission to request an Authority Required listing for the treatment of severe chronic plaque psoriasis. |
| New listing<br><br>(Minor Submission) | INSULINE GLARGINE<br><br>Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5<br><br>Semglee®<br><br>Alphapharm Pty Ltd | Unrestricted (indicated for diabetes mellitus) | To request an unrestricted benefit listing for this biosimilar brand for all indications for which the reference biological is currently PBS listed. |

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| Change to listing<br><br>(Major Submission) | IXEKIZUMAB<br><br>Injection 80 mg in 1 mL single dose pre-filled pen<br>Injection 80 mg in 1 mL single dose pre-filled syringe<br><br>Taltz®<br><br>Eli Lilly Australia Pty Ltd | Severe active psoriatic arthritis | To request an Authority Required listing for the treatment of severe active psoriatic arthritis. |
| Change to listing<br><br>(Major Submission) | LENVATINIB<br><br>Capsule 4 mg (as mesilate)<br><br>Lenvima®<br><br>Eisai Australia Pty Ltd | Unresectable hepatocellular carcinoma | To request an Authority Required (STREAMLINED) listing for the treatment of unresectable hepatocellular carcinoma. |
| Change to listing<br><br>(Minor Submission) | LENVATINIB<br><br>Capsule 4 mg (as mesilate)<br>Capsule 10 mg (as mesilate)<br><br>Lenvima®<br><br>Eisai Australia Pty Ltd | Locally advanced or metastatic differentiated thyroid cancer | To request a change to the maximum quantity for the current Authority Required (STREAMLINED) listing. |
| New listing<br><br>(Major Submission) | LETERMOVIR<br><br>Tablet 240 mg<br><br>Prevymis®<br><br>Merck Sharp & Dohme (Australia) Pty Ltd | Prophylaxis of cytomegalovirus (CMV) infection or disease | To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the prophylaxis of cytomegalovirus (CMV) infection or disease in adult CMV-seropositive [R+] recipients of an allogeneic haematopoietic stem cell transplant (allo-HSCT). |

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| New listing<br><br>(Minor Submission)<br><br>WITHDRAWN | LEVOCARNITINE<br><br>Capsule 500 mg<br><br>Metabolics L-Carnitine®<br><br>KMC Health Care | Primary systemic carnitine deficiency; Secondary deficiency in patients with inborn errors of metabolism | To request a Restricted Benefit listing for the treatment of primary systemic carnitine deficiency and secondary carnitine deficiency in patients with inborn errors of metabolism. |
| New listing<br><br>(Major Submission) | LUMACAFTOR with IVACAFTOR<br><br>Tablet containing lumacaftor 100 mg with ivacaftor 125 mg<br><br>Orkambi®<br><br>Vertex Pharmaceuticals (Australia) Pty Ltd | Cystic fibrosis | To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of cystic fibrosis in patients aged between 6 years and 11 years who are homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene. |
| New listing<br><br>(Major Submission) | LUMACAFTOR with IVACAFTOR<br><br>Tablet containing lumacaftor 200 mg with ivacaftor 125 mg<br><br>Orkambi®<br><br>Vertex Pharmaceuticals (Australia) Pty Ltd | Cystic fibrosis | Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of cystic fibrosis in patients aged 12 years and over who are homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene. |
| New listing<br><br>(Major Submission) | MENINGOCOCCAL POLYSACCHARIDE SEROGROUPS A, C, W-135 AND Y CONJUGATE VACCINE<br><br>Injection 0.5mL combination pack<br><br>Menveo®<br><br>GlaxoSmithKline Australia Pty Ltd | Meningococcal disease | To request listing on the National Immunisation Program (NIP) for the immunisation of adolescents aged approximately 15 years of age (Year 9 or 10 students), with a catch-up program for school-aged adolescents/young adults aged up to and including 19 years, delivered through a combination of strategies including school-based delivery and via primary care providers. |

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| New listing<br><br>(Minor Submission) | MESALAZINE<br><br>Tablet 1 g (enteric coated)<br><br>Salofalk®<br><br>Orphan Australia Pty Ltd | Ulcerative colitis<br>Crohn disease | To request an Authority Required (STREAMLINED) listing for a new strength of mesalazine for the treatment of ulcerative colitis and Crohn disease. |
| New listing<br><br>(Minor Submission) | METHOTREXATE<br><br>Injection 7.5 mg in 0.3 mL pre-filled syringe<br>Injection 10 mg in 0.4 mL pre-filled syringe<br>Injection 15 mg in 0.6 mL pre-filled syringe<br>Injection 20 mg in 0.8 mL pre-filled syringe<br>Injection 25 mg in 1 mL pre-filled syringe<br><br>Methoblastin® PFS<br><br>Pfizer Australia Pty Ltd | Severe active rheumatoid arthritis;<br>Severe psoriasis | To request an Authority Required (STREAMLINED) listing for treatment of patients with severe active rheumatoid arthritis and severe psoriasis. |
| New listing<br><br>(Major Submission) | MIDOSTAURIN<br><br>Capsule 25 mg<br><br>Rydapt®<br><br>Novartis Pharmaceuticals Australia Pty Ltd | Acute myeloid leukaemia (AML) | Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required listing of midostaurin for the treatment of patients with newly diagnosed FMS-like tyrosine kinase 3 (FLT3) mutation positive acute myeloid leukaemia (AML). |
| New listing<br><br>(Major Submission) | NIVOLUMAB and IPILIMUMAB<br><br>Nivolumab:<br>Injection concentrate for I.V. infusion 40 mg in 4 mL<br>Injection concentrate for I.V. infusion 100 mg | Renal cell carcinoma (RCC) | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STEAMLINED) listing for the concurrent use of nivolumab and ipilimumab for the treatment of Stage IV clear cell variant renal cell carcinoma (RCC). |

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|---|---|---|---|
| | in 10 mL<br>Ipilimumab:<br>Injection concentrate for I.V. infusion 50 mg in 10 mL<br>Injection concentrate for I.V. infusion 200 mg in 40 mL<br><br>Opdivo® and Yervoy®<br><br>Bristol-Myers Squibb Australia Pty Ltd | | |
| New listing<br><br>(Major Submission) | NIVOLUMAB and IPILIMUMAB<br><br>Nivolumab:<br>Injection concentrate for I.V. infusion 40 mg in 4 mL<br>Injection concentrate for I.V. infusion 100 mg in 10 mL<br>Ipilimumab:<br>Injection concentrate for I.V. infusion 50 mg in 10 mL<br>Injection concentrate for I.V. infusion 200 mg in 40 mL<br><br>Opdivo® and Yervoy®<br><br>Bristol-Myers Squibb Australia Pty Ltd | Malignant melanoma | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the concurrent use of nivolumab and ipilimumab for the treatment of unresectable Stage III or Stage IV malignant melanoma. |
| Change to listing<br><br>(Major Submission) | NIVOLUMAB<br><br>Injection concentrate for I.V. infusion 40 mg in 4 mL<br>Injection concentrate for I.V. infusion 100 mg in 10 mL | Malignant melanoma | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the adjuvant treatment of patients who have had completely surgically resected Stage III or Stage IV malignant melanoma. |

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|---|---|---|---|
| | Opdivo®<br><br>Bristol-Myers Squibb Australia Pty Ltd | | |
| Change to listing<br><br>(Minor Submission) | OBINUTUZUMAB<br><br>Solution for I.V. infusion 1000 mg in 40 mL<br><br>Gazvya®<br><br>Roche Products Pty Ltd | Chronic lymphocytic leukaemia (CLL) | To request that the current listings be changed to Authority Required (STREAMLINED). |
| Change to listing<br><br>(Minor Submission) | OCTREOTIDE<br><br>Injection (modified release) 10 mg (as acetate), vial and diluent syringe<br>Injection (modified release) 20 mg (as acetate), vial and diluent syringe<br>Injection (modified release) 30 mg (as acetate), vial and diluent syringe<br><br>Sandostatin LAR®<br><br>Novartis Pharmaceuticals Australia Pty Ltd | Functional carcinoid tumour;<br>Acromegaly;<br>Vasoactive intestinal peptide secreting tumour (VIPoma) | To request that the current listing supply arrangements be expanded to include Section 100 (Highly Specialised Drugs Program - Community Access) Authority Required (STREAMLINED) listings. |
| New listing<br><br>(Major Submission) | OSIMERTINIB<br><br>Tablet 40 mg<br>Tablet 80 mg<br><br>Tagrisso®<br><br>Astra Zeneca Pty Ltd | Locally advanced (Stage IIIB) or metastatic (Stage IV) epidermal growth factor receptor (EGFR) T790M mutation positive non-small cell lung cancer (NSCLC) | Resubmission to request an Authority Required listing for the treatment of patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation positive non-small cell lung cancer (NSCLC) who have progressed on or after prior treatment with an EGFR tyrosine kinase inhibitor (TKI). |

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|---|---|---|---|
| New listing<br><br>(Minor Submission) | PEGFILGRASTIM<br><br>Injection 6 mg in 0.6 mL single use pre-filled syringe<br><br>Fulphila®<br><br>Alphapharm Pty Ltd | Chemotherapy-induced neutropenia | To request a Section 100 (Highly Specialised Drug) Authority Required (STREAMLINED) listing of this biosimilar brand for all indications for which the reference biologic is currently PBS listed. |
| Change to listing<br><br>(Major Submission) | PEMBROLIZUMAB<br><br>Solution concentrate for I.V. infusion 100 mg in 4 mL<br><br>Keytruda®<br><br>Merck Sharp & Dohme (Australia) Pty Ltd | Squamous cell carcinoma for the head and neck (SCCHN) | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of patients with recurrent or metastatic squamous cell carcinoma for the head and neck (SCCHN) who progress on or after platinum-based chemotherapy. |
| Change to listing<br><br>(Minor Submission) | PEMBROLIZUMAB<br><br>Powder for injection 50 mg<br>Solution concentrate for I.V. infusion 100 mg in 4 mL<br><br>Keytruda®<br><br>Merck, Sharp & Dohme (Australia) Pty Ltd | First-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing as first line monotherapy in patients expressing PD-L1 for NSCLC. |

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|---|---|---|---|
| Change to listing<br><br>(Major Submission) | PEMBROLIZUMAB<br><br>Solution concentrate for I.V. infusion 100 mg in 4 mL<br><br>Keytruda®<br><br>Merck Sharp & Dohme (Australia) Pty Ltd | Locally advanced or metastatic urothelial cancer | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of locally advanced or metastatic urothelial cancer after the failure of a prior platinum-based chemotherapy. |
| New listing<br><br>(Major Submission) | PERTUZUMAB<br><br>Solution for I.V. infusion 420 mg in 14 mL<br><br>Perjeta®<br><br>Roche Products Pty Ltd | Human epidermal growth factor receptor-2 positive (HER2+) early breast cancer (EBC) | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the adjuvant treatment of HER2+, lymph node positive early breast cancer (EBC). |
| New listing<br><br>(Minor Submission)<br><br><br><br>WITHDRAWN | RITUXIMAB<br><br>Solution for I.V. infusion 100 mg in 10 mL<br>Solution for I.V. infusion 500 mg in 50 mL<br><br>Truxima®<br><br>Celltrion Healthcare Australia Pty Ltd | Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma; Severe active granulomatosis with polyangiitis (Wegener's granulomatosis); Severe active microscopic polyangiitis; Previously untreated or relapsed/refractory CD20 positive lymphoid cancer; Previously untreated or Relapsed/refractory CD20 positive acute lymphoblastic leukaemia; Severe active rheumatoid arthritis | To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) and Section 100 Authority Required (Highly Specialised Drug) listings for this biosimilar brand for all indications for which the reference biological is currently PBS listed. |

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|---|---|---|---|
| New listing<br><br>(Minor Submission) | SOMATROPIN<br><br>Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative)<br><br>SciTropin A™<br><br>SciGen (Australia) Pty Ltd | Growth disturbance due to insufficient secretion of pituitary growth hormone, or growth disturbance associated with gonadal dysgenesis (Turner syndrome) or chronic renal insufficiency | To request an Authority Required listing of an additional strength of somatropin injection. |
| New listing<br><br>(Major Submission) | TEDUGLUTIDE<br><br>Powder for injection 5 mg with diluent<br><br>Revestive®<br><br>Shire Australia Pty Limited | Short Bowel Syndrome (SBS) | Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for the treatment of short bowel syndrome (SBS) in patients who are dependent on parenteral nutrition for survival. |
| New listing<br><br>(Major Submission) | TILDRAKIZUMAB<br><br>Injection 100 mg in 1 mL single use pre-filled syringe<br><br>Ilumy®<br><br>Sun Pharma ANZ Pty Ltd | Severe chronic plaque psoriasis | To request an Authority Required listing for the treatment of patients with severe chronic plaque psoriasis. |
| New listing<br><br>(Minor Submission) | TOCILIZUMAB<br><br>Injection 162 mg in 0.9 mL pre-filled pen<br><br>Actemra® Subcutaneous Injection<br><br>Roche Products Pty Ltd | Severe active rheumatoid arthritis | To request an Authority Required listing of a new form of subcutaneous tocilizumab. |

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|---|---|---|---|
| New listing<br><br>(Minor Submission) | TOLVAPTAN<br><br>Pack containing 28 tablets 15 mg and 28 tablets 45 mg<br>Pack containing 28 tablets 30 mg and 28 tablets 60 mg<br>Pack containing 28 tablets 30 mg and 28 tablets 90 mg<br><br>Jinarc®<br><br>Otsuka Australia Pharmaceutical Pty Ltd | Autosomal dominant polycystic kidney disease (ADPKD) | Resubmission to request an Authority Required listing for the treatment of autosomal dominant polycystic kidney disease (ADPKD). |
| New listing<br><br>(Minor Submission) | TRIFLURIDINE + TIPIRACIL<br><br>Tablet containing 15 mg trifluridine with 6.14 mg tipiracil (as hydrochloride)<br>Tablet containing 20 mg trifluridine with 8.19 mg tipiracil (as hydrochloride)<br><br>LONSURF®<br><br>Servier Laboratories (Australia) Pty Ltd | Metastatic colorectal cancer | Resubmission to request an Authority Required (STREAMLINED) listing for adult patients with metastatic colorectal cancer. |
| Change to listing<br><br>(Minor Submission) | TRIGLYCERIDES MEDIUM CHAIN FORMULA<br><br>Sachets containing oral powder 16 g, 30 (MCT Pro-Cal)<br><br>MCT Pro-Cal<br><br>Vitaflo Australia Pty Limited | Chylous ascites;<br>Chylothorax;<br>Fat malabsorption;<br>Hyperlipoproteinanaemia type 1;<br>Long chain fatty acid oxidation disorders | To request a minor formulation change and new age restriction for the existing Authority Required (STREAMLINED) listing of MCT Pro-Cal. |

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|---|---|---|---|
| Change to listing<br><br>(Major Submission) | TRIVALENT INFLUENZA VACCINE (High dose)<br><br>Injection 0.5 mL<br><br>Fluzone® High-Dose<br><br>Sanofi-aventis Australia Pty Ltd | Prevention of seasonal influenza | To request that the PBAC review the circumstances of the recommended National Immunisation Program (NIP) listing for the prevention of seasonal influenza in patients aged 65 years and over. |
| Sub-committee report<br><br>(DUSC Analysis) | Aflibercept (Eylea®, Bayer Australia Ltd)<br>Dexamethasone implant (Ozurdex®, Allergan Australia Pty Limited)<br>Ranibizumab (Lucentis®, Novartis Pharmaceuticals Australia Pty Limited) | Age-related Macular Degeneration (AMD);<br>Retinal Vein Occlusion (RVO);<br>Diabetic Macular Oedema (DMO) | To consider the use of ranibizumab and aflibercept for AMD since it was last reviewed in 2015.<br><br>To assess the use of ranibizumab and aflibercept for DMO and RVO in the first 24 months of listing. Use of dexamethasone implant for DMO will also be considered in this analysis. |
| Sub-committee report<br><br>(DUSC Analysis) | Cobimetinib (Cotellic®, Roche Products Pty Ltd)<br>Dabrafenib (Tafinlar®, Novartis Pharmaceuticals Australia Pty Limited)<br>Ipilimumab (Yervoy®, Bristol-Myers Squibb Australia Pty Ltd)<br>Nivolumab (Opdivo®, Bristol-Myers Squibb Australia Pty Ltd)<br>Pembrolizumab (Keytruda®, Merck Sharp & Dohme (Australia) Pty Ltd)<br>Trametinib (Mekinist®, Novartis Pharmaceuticals Australia Pty Limited)<br>Vemurafenib (Zelboraf®, Roche Products Pty Ltd) | Targeted and immunomodulatory therapies for metastatic melanoma | To assess the use of targeted and immunomodulatory medicines for the treatment of unresectable stage III or metastatic (stage IV) malignant melanoma. |

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|---|---|---|---|
| Sub-committee report<br><br>(DUSC Analysis) | Dexamfetamine (Aspen Pharma Pty Ltd)<br>Methylphenidate (Ritalin 10® and Artige®, Novartis Pharmaceuticals Australia Pty Limited)<br>Methylphenidate modified release (Concerta®, Janssen-Cilag Pty Ltd), (Ritalin LA®, Novartis Pharmaceuticals Australia Pty Limited)<br>Atomoxetine (Strattera®, Eli Lilly Pty Ltd)<br>Lisdexamfetamine (Vyvanse®, Shire Australia Pty Ltd) | Attention Deficit Hyperactivity Disorder (ADHD) | To consider a drug utilisation review of medicines for the treatment of ADHD; and to compare the predicted and actual use of lisdexamfetamine in the first 24 months of PBS listing. |
| Sub-committee report<br><br>(DUSC Analysis) | Botulinum toxin type A (Botox®, Allergan Australia Pty Limited)<br>Clostridium botulinum type A toxin-haemagglutinin complex (Dysport®, Ipsen Pty Ltd)<br>IncobotulinumtoxinA (Xeomin®, Merz Australia Pty Ltd) | Botulinum toxin (for spasticity, spasmodic torticollis (cervical dystonia), blepharospasm and hemifacial spasm) | To assess the use of botulinum toxin for the treatment of spasticity, spasmodic torticollis (cervical dystonia), blepharospasm and hemifacial spasm. |
| Matters relating to PBS Utilisation Review of Proton Pump Inhibitors (PPIs) | Omeprazole<br>Pantoprazole<br>Lansoprazole<br>Rabeprazole<br>Esomeprazole<br><br>(all listed brands and strengths) | Gastro-oesophageal reflux disorders | To consider restriction amendments for PPI medicines, as requested by PBAC following consideration of the utilisation review of all PBS listed PPI medicines in March 2018. |
| Sub-committee report<br><br>(DUSC Analysis) | Posaconazole (Noxafil®, Merck Sharp & Dohme (Australia) Pty Ltd) | Treatment and prophylaxis of fungal infections | To compare the predicted and actual use of posaconazole for the treatment and prophylaxis of fungal infections since the tablet form was PBS listed in September 2015. |