|  |
| --- |
| 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. |

| **Submission type** (new listing, change to listing) | **Drug Name, form(s), strength(s) and Sponsor** (Drug name, form, strength, Trade name®, Sponsor) | **Drug Type and Use** (What is the drug used to treat?) | **Listing requested by Sponsor / Purpose of Submission** (Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased.) |
| --- | --- | --- | --- |
| New listing  (Minor Submission) | ADALIMUMAB  Injection 40 mg pre-filled pen  Injection 40 mg pre-filled syringe  Injection 40 mg vial  Idacio®  Fresenius Kabi Australia Pty Limited | Severe Crohn disease; moderate to severe ulcerative colitis; severe active juvenile idiopathic arthritis; complex refractory fistulising Crohn disease; severe active rheumatoid arthritis; severe psoriatic arthritis; ankylosing spondylitis; severe chronic plaque psoriasis; moderate to severe hidradenitis suppurativa | To request an Authority Required (STREAMLINED) listing of a new biosimilar adalimumab under the same conditions as the reference biologic. |
| Change to listing  (Minor Submission) | ADALIMUMAB  Injection 40 mg pre-filled syringe  Injection 40 mg auto-injector  Hadlima®  Merck Sharp & Dohme (Australia) Pty Ltd | Severe Crohn disease; complex refractory fistulising Crohn disease; moderate to severe ulcerative colitis; severe active juvenile idiopathic arthritis; adult patients with a history of juvenile idiopathic arthritis; severe psoriatic arthritis; ankylosing spondylitis; severe chronic plaque psoriasis; severe active rheumatoid arthritis | To request an Authority Required (STREAMLINED) listing for the biosimilar in the continuing treatment phase; to request an Authority Required (telephone) for the biosimilar in the initial treatment phase; and to request that use of the biosimilar not count as treatment failure. |
| New listing  (Minor Submission) | ADRENALINE  I.M. injection 150 micrograms in 0.3 mL single dose syringe auto-injector  I.M. injection 300 micrograms in 0.3 mL single dose syringe auto-injector  I.M. injection 500 micrograms in 0.3 mL single dose syringe auto-injector  Anapen®  Allergy Concepts Pty Ltd | Acute allergic reaction with anaphylaxis | To request the Authority Required listing of an alternative brand of adrenaline auto-injector under the same conditions as other brands of adrenaline currently listed on the PBS and to request the Authority Required listing of a new strength of adrenaline auto-injector. |
| New listing  (Minor Submission) | AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN  Sachets containing oral powder 24 g  Sachets containing oral powder 25 g  GA Gel®  GA Express 15®  Vitaflo Australia Pty Limited | Pyridoxine dependent epilepsy | To request a Restricted Benefit listing for the management of pyridoxine dependent epilepsy. |
| New listing  (Major Submission) | APALUTAMIDE  Tablet 60 mg  Erlyand®  Janssen-Cilag Pty Ltd | Prostate cancer | Resubmission to request an Authority Required (Telephone) listing for the treatment of castration resistant prostate cancer with no distant metastasis on conventional imaging. |
| Change to listing  (Minor Submission) | APOMORPHINE  Solution for subcutaneous infusion containing apomorphine hydrochloride hemihydrate 50 mg in 10 mL pre-filled syringe  Movapo PFS®  Stada Pharmaceuticals Australia Pty Limited | Parkinson’s disease | To request General Schedule, Authority Required (STREAMLINED) listing for the continuing treatment of Parkinson’s disease following initiation with the current Section 100 (Highly Specialised Drugs Program) listings. |
| New listing  (Major Submission) | BECLOMETASONE DIPROPIONATE + FORMOTEROL FUMARATE DIHYDRATE + GYLCOPYRRONIUM  Pressurised inhalation containing beclometasone dipropionate 100 micrograms with formoterol fumarate dihydrate 6 micrograms and glycopyrronium 10 micrograms (as bromide) per dose, 120 doses  Trimbow®  Chiesi Australia Pty Ltd | Chronic obstructive pulmonary disease (COPD) | To request an Authority Required (STREAMLINED) listing for maintenance treatment of moderate to severe COPD. |
| New listing  (Minor Submission) | BEVACIZUMAB  Solution for I.V. infusion 100 mg in 4 mL  Solution for I.V. infusion 400 mg in 16 mL  MVASI®  Amgen Australia Pty Limited | Metastatic colorectal cancer (mCRC); advanced stage IIIB, IIIC or stage IV epithelial ovarian, fallopian tube, or primary peritoneal cancer; advanced carcinoma of the cervix; stage IV (metastatic) non-small cell lung cancer (NSCLC); relapsed or recurrent glioblastoma | To request Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing of a new biosimilar bevacizumab under the same conditions as the reference biologic. |
| Change to listing  (Major Submission) | CABOZANTINIB  Tablet 20 mg  Tablet 40 mg  Tablet 60 mg  Cabometyx®  Ipsen Pty Ltd | Renal cell carcinoma (RCC) | Resubmission to request an extension to the current Authority Required (STREAMLINED) listing for the treatment of Stage IV clear cell variant RCC to include patients who have not been previously treated with a tyrosine kinase inhibitor (TKI). |
| New listing  (Major Submission) | CARIPRAZINE  Capsule 1.5 mg  Capsule 3 mg  Capsule 4.5 mg  Capsule 6 mg  Reagila®  Seqirus (Australia) Pty Ltd | Schizophrenia | To request an Authority Required (STREAMLINED) listing for the treatment of schizophrenia. |
| New listing  (Major Submission) | CEMIPLIMAB  Solution for IV infusion 350 mg in 7 mL  Libtayo®  Sanofi-Aventis Australia Pty Ltd | Squamous cell carcinoma (SCC) | To request Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of metastatic or locally advanced cutaneous SCC in patients who are not candidates for curative surgery or curative radiation. |
| New listing  (Major Submission) | CRISABOROLE  Ointment 2%, 30 g  Ointment 2%, 60 g  Staquis®  Pfizer Australia Pty Ltd | Atopic dermatitis | Resubmission to request an Authority Required (STREAMLINED) listing for the treatment of mild to moderate atopic dermatitis. |
| Change to listing  (Major Submission) | DAPAGLIFLOZIN  Tablet 10 mg  Forxiga®  AstraZeneca Pty Ltd | Heart failure | To request an extension of the current Authority Required (STREAMLINED) listing to include the treatment of heart failure in patients with reduced ejection fraction. |
| New listing  (Minor Submission) | DEFERASIROX  Dispersible tablet 125 mg  Dispersible tablet 250 mg  Dispersible tablet 500 mg  Deferasirox Juno®  Juno Pharmaceuticals Pty Ltd | Chronic iron overload | To request a Section 100 (Highly Specialised Drugs Program) Authority Required listing for a new form of deferasirox for the treatment of chronic iron overload. |
| Change to listing  (Major Submission) | 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 | Asthma | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of severe uncontrolled asthma. |
| New listing  (Other) | DUPILUMAB  Injection 200 mg in 1.14 mL single use pre-filled syringe  Injection 300 mg in 2 mL single use pre-filled syringe  Dupixent®  Sanofi-Aventis Australia Pty Ltd | Atopic dermatitis | To request that the PBAC review a revised proposal following the March 2020 recommendation for dupliumab for the treatment of patients with chronic severe atopic dermatitis who have had an inadequate response to topical therapies. |
| Change to listing  (Major Submission) | DURVALUMAB  Solution concentrate for I.V. infusion 120 mg in 2.4 mL  Solution concentrate for I.V. infusion 500 mg in 10 mL  Imfinzi®  AstraZeneca Pty Ltd | Small cell lung cancer (SCLC) | To request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (STREAMLINED) listing in combination with etoposide and platinum-based  chemotherapy for the first-line treatment of extensive-stage SCLC. |
| Change to listing  (Major Submission) | ECULIZUMAB  Solution concentrate for I.V. infusion 300 mg in 30 mL  Soliris®  Alexion Pharmaceuticals Australasia Pty Ltd | Neuromyelitis optica spectrum disorder (NMOSD) | To request an Authority Required (Written) listing for the treatment of patients with relapsing NMOSD who are anti-aquaporin-4 (AQP4) antibody positive. |
| New listing  (Major Submission) | ELOTUZUMAB  Powder for IV infusion 300 mg  Powder for IV infusion 400 mg  Empliciti®  Bristol-Myers Squibb Australia Pty Ltd | Multiple myeloma | To request Section 100 (Efficient Funding of Chemotherapy) Authority Required (Telephone) listing in combination with lenalidomide and dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma. |
| Change to listing  (Minor Submission) | EVOLOCUMAB  Injection 140 mg in 1 mL single use pre-filled pen  Injection 420 mg in 3.5 mL single use pre-filled cartridge  Repatha®  Amgen Australia Pty Limited | Familial heterozygous hypercholesterolaemia;  Non-familial hypercholesterolaemia; Familial homozygous hypercholesterolaemia | To request an amendment to the Authority Required listing to allow general practitioners to initiate treatment in consultation with a specialist. |
| New listing  (Major Submission)  WITHDRAWN | FILGOTINIB  Tablet 100 mg  Tablet 200 mg  Jyseleca®  Gilead Sciences Pty Ltd | Rheumatoid arthritis | To request an Authority Required (Written) listing for the treatment of severe active rheumatoid arthritis. |
| New listing  (Minor Submission) | FLUOCINOLONE ACETONIDE  Intravitreal injection 190 micrograms  Iluvien®  Specialised Therapeutics Alim Pty Ltd | Diabetic macular oedema | Resubmission to request an amendment to the PBAC’s previously recommended equi-effective doses for fluocinolone acetonide and dexamethasone. |
| New listing  (Major Submission) | GALCANEZUMAB  Injection 120 mg in 1 mL pre-filled pen  Emgality®  Eli Lilly Australia Pty Ltd | Episodic migraine | To request an Authority Required (STREAMLINED) listing for the treatment of adult patients with treatment-resistant episodic migraine. |
| New listing  (Minor Submission) | GALCANEZUMAB  Injection 120 mg in 1 mL pre-filled pen  Emgality®  Eli Lilly Australia Pty Ltd | Chronic migraine | Resubmission to request an Authority Required (STREAMLINED) listing for the prophylactic treatment of patients with chronic migraine who have experienced inadequate response, intolerance or a contraindication to at least three prior preventive migraine medications. |
| Change to listing  (Minor Submission) | GLECAPREVIR + PIBRENTASVIR  Tablet containing 100 mg glecaprevir with 40 mg pibrentasvir  Maviret®  AbbVie Pty Ltd | Chronic hepatitis C infection | To request an amendment to the Section 100 (Highly Specialised Drugs Program) and General Schedule Authority Required listings to reduce the duration of treatment from 12 weeks to 8 weeks for treatment naïve patients with chronic hepatitis C with compensated cirrhosis. |
| Change to listing  (Major Submission) | GUSELKUMAB  Injection 100 mg in 1 mL single use pre-filled syringe  Injection 100 mg in 1 mL single use pre-filled pen  Tremfya®  Janssen-Cilag Pty Ltd | Psoriatic arthritis | To request an Authority Required (Written) listing for the treatment of adult patients with severe psoriatic arthritis who have had an inadequate response to methotrexate and sulfasalazine or leflunomide. |
| New listing  (Minor Submission) | HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE  Oral liquid 250 mL, 30  KetoVie 4:1®  KetoVie 3:1®  KetoVie Peptide 4:1®  Cortex Health Pty Ltd | Ketogenic diet | To request a Restricted Benefit listing for KetoVie 4:1 and 3:1 and an Authority Required (STREAMLINED) listing for KetoVie Peptide 4:1 as part of a ketogenic diet. |
| New listing  (Minor Submission) | IBRUTINIB  Tablet 140 mg  Tablet 280 mg  Tablet 420 mg  Tablet 560 mg  Imbruvica®  Janssen-Cilag Pty Ltd | Chronic lymphocytic leukaemia (CLL); small lymphocytic lymphoma (SLL); mantle cell lymphoma | To request an Authority Required listing of ibrutinib tablet under the same conditions as the already listed capsule. |
| New listing  (Major Submission) | INFLIXIMAB  Injection 120 mg in 1 mL pre-filled syringe  Injection 120 mg in 1 mL pre-filled pen  Remsima® SC  Celltrion Healthcare Australia Pty Ltd | Rheumatoid arthritis  Ankylosing spondylitis  Psoriatic arthritis  Chronic plaque psoriasis  Crohn’s disease  Complex refractory fistulising Crohn’s disease  Ulcerative colitis | To request Section 100 (Highly Specialised Drugs Program) and Authority Required listings under the same conditions as infliximab powder for I.V. infusion 100 mg. |
| New listing  (Major Submission) | IXAZOMIB  Capsule 2.3 mg  Capsule 3 mg  Capsule 4 mg  Ninlaro®  Takeda Pharmaceuticals Australia Pty Ltd | Multiple myeloma | To request Section 100 (Highly Specialised Drugs Program) Authority Required (Telephone) listing in combination with lenalidomide and dexamethasone for patients with relapsed or refractory multiple myeloma. |
| New listing  (Major Submission) | LAROTRECTINIB  Capsule 25 mg  Capsule 100 mg  Oral solution 20 mg per mL, 100 mL  Vitrakvi®  Bayer Australia Ltd | Solid tumours harbouring neurotrophic receptor tyrosine kinase (NTRK) gene fusions | To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of locally advanced or metastatic solid tumours harbouring NTRK gene fusions. |
| New listing  (Major Submission) | MENINGOCOCCAL POLYSACCHARIDE SEROGROUPS A, C, W-135 AND Y CONJUGATE VACCINE  Injection 0.5 mL  MenQuadfi®  Sanofi-Aventis Australia Pty Ltd | Prevention of meningococcal disease | To request National Immunisation Program (NIP) listing for the prevention of meningococcal disease in toddler and adolescent populations. |
| New listing  (Minor Submission) | MESALAZINE  Tablet 1600 mg  Asacol®  Chiesi Australia Pty Ltd | Ulcerative colitis | To request a Restricted Benefit listing of mesalazine for the treatment of mild to moderate ulcerative colitis and maintenance of remission in adults. |
| New listing  (Minor Submission) | MOGAMULIZUMAB  Solution concentrate for I.V. infusion 20 mg in 5 mL  Poteligeo®  Kyowa Kirin Australia Pty Ltd | Cutaneous T-Cell Lymphoma (CTCL) | Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (Written) listing for patients with relapsed or refractory CTCL who have previously been treated with at least one prior systemic therapy. |
| Change to listing  (Major Submission) | NIVOLUMAB  IPILIMUMAB  Nivolumab:  Injection concentrate for I.V. infusion 40 mg in 4 mL  Injection concentrate for I.V. infusion 100 mg in 10 mL  Opdivo®  Ipilimumab:  Injection concentrate for I.V. infusion 50 mg in 10 mL  Yervoy®  Bristol-Myers Squibb Australia Pty Ltd | Non-small cell lung cancer (NSCLC) | To request Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing in combination with two cycles of chemotherapy for the first-line treatment of patients with Stage IV (metastatic) NSCLC. |
| Change to listing  (Major Submission) | NUSINERSEN  Solution for injection 12 mg in 5 mL  Spinraza®  Biogen Australia Pty Ltd | Spinal muscular atrophy (SMA) | Resubmission to request an extension to the current Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing to include the treatment of adults with SMA. |
| New listing  (Major Submission) | OBETICHOLIC ACID  Tablet 5 mg  Tablet 10 mg  Ocaliva®  Chiesi Australia Pty Ltd | Primary biliary cholangitis | Resubmission to request an Authority Required (Written) listing for the treatment of primary biliary cholangitis. |
| New listing  (Major Submission) | ONASEMNOGENE ABEPARVOVEC  Solution for injection, customised based on patient weight  Zolgensma®  Novartis Pharmaceuticals Australia Pty Ltd | Spinal muscular atrophy (SMA) | Submission to request an Authority Required (Written) listing for the treatment of paediatric patients less than 2 years of age with Type 1 SMA. |
| New listing  (Minor Submission) | PANCREATIC EXTRACT  Capsule (containing enteric coated minimicrospheres) providing not less than 20,000 BP units of lipase activity  Capsule (containing enteric coated minimicrospheres) providing not less than 35,000 BP units of lipase activity  Creon®  Mylan Health Pty Ltd | Pancreatic exocrine insufficiency | To request an Unrestricted Benefit listing under the same conditions as the already listed strengths. |
| New listing  (Major Submission) | PATIROMER  Sachet, 8.4 g powder for oral liquid  Sachet, 16.8 g powder for oral liquid  Veltassa®  Vifor Pharma Pty Ltd | Hyperkalaemia | Resubmission to request an Authority Required (Telephone) listing for the prevention of hyperkalaemia in patients with stage III or greater chronic kidney disease who have experienced a recent episode of hyperkalaemia requiring pharmacological intervention. |
| Change to listing  (Major Submission) | PEMBROLIZUMAB  Solution concentrate for I.V. infusion 100 mg in 4 mL  Keytruda®  Merck Sharp & Dohme (Australia) Pty Ltd | Squamous cell carcinoma of the head and neck (SCCHN) | To request Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the first line treatment of recurrent or metastatic SCCHN. |
| Change to listing  (Major Submission) | PROGESTERONE  Capsule 200 mg  Utrogestan®  Besins Healthcare Australia Pty Ltd | Prevention of preterm birth | To request an extension of the current Authority Required (STREAMLINED) listing to include the prevention of preterm birth in women at risk. |
| Change to listing  (Major Submission) | PROGESTERONE  Pessary 200 mg  Oripro®  Orion Laboratories Pty Ltd | Prevention of preterm birth | To request an extension of the current Authority Required (STREAMLINED) listing to include the prevention of preterm birth in women at risk. |
| Change to listing  (Minor Submission) | RIBOCICLIB  Tablet 200 mg  Kisqali®  Novartis Pharmaceuticals Australia Pty Ltd | Locally advanced or metastatic breast cancer | Resubmission to request an Authority Required listing for the treatment of postmenopausal women with hormone receptor positive (HR+), human epidermal growth factor receptor 2 negative (HER2-) advanced or metastatic breast cancer in combination with fulvestrant. |
| Change to listing  (Major Submission) | SACUBITRIL with VALSARTAN  Tablet containing sacubitril 24.3 mg + valsartan 25.7 mg  Tablet containing sacubitril 48.6 mg + valsartan 51.4 mg  Tablet containing sacubitril 97.2 mg + valsartan 102.8 mg  Entresto®  Novartis Pharmaceuticals Australia Pty Ltd | Heart failure | To request changes to the current Authority Required (STREAMLINED) listing for patients with chronic heart failure with reduced ejection fraction (HF-rEF) to include a broader population of patients. |
| Change to listing  (Minor Submission) | SAPROPTERIN  Powder for oral solution 500 mg  Tablet (soluble) 100 mg  Kuvan®  Biomarin Pharmaceutical Australia Pty Ltd | Maternal phenylketonuria (MPKU) | Resubmission to request an Authority Required listing in combination with a Phe-restricted diet for the treatment of MPKU where a Phe-restricted diet does not adequately reduce blood Phe levels. |
| Change to listing  (Major Submission) | SECUKINUMAB  Injection 150 mg in 1 mL pre-filled pen  Cosentyx®  Novartis Pharmaceuticals Australia Pty Ltd | Non-radiographic axial spondyloarthritis (nr-axSpA) | To request an Authority Required (Written) listing for the treatment of nr-axSpA. |
| Change to listing  (Major and Minor Submissions) | TOFACITINIB  Tablet 5 mg  Tablet 10 mg  Xeljanz®  Pfizer Australia Pty Ltd | Ulcerative colitis and other listed indications | Resubmission to request an Authority Required (Written) listing for the treatment of moderate to severe ulcerative colitis and separate submission to consider interchangeability advice. |
| Change to listing  (Minor Submission) | UPADACITINIB  Tablet 15 mg  Rinvoq®  Abbvie Pty Ltd | Severe rheumatoid arthritis | Resubmission to request review of the statistical basis upon which the claim of superior effectiveness versus adalimumab for the treatment of patients with severe active RA was not accepted. |
| New listing  (Major Submission) | VEDOLIZUMAB  Injection 108 mg in 0.68 mL pre-filled syringe  Injection 108 mg in 0.68 mL pre-filled pen  Entyvio®  Takeda Pharmaceuticals Australia Pty Ltd | Ulcerative colitis  Crohn's disease | To request Authority Required listings under the same conditions as vedolizumab powder for injection 300 mg. |
| Sub-committee report  (DUSC Analysis) | ADRENALINE  I.M. injection 150 micrograms in 0.3 mL single dose syringe auto-injector  I.M. injection 300 microgram in 0.3 mL single dose syringe auto-injector  Epipen®, Adrenaline Mylan®  Alphapharm Pty Ltd | Treatment of allergic reaction with anaphylaxis | To assess the utilisation of PBS listed adrenaline for the treatment of allergic reaction with anaphylaxis. |
| Sub-committee report  (DUSC Analysis) | ALECTINIB  Capsule 150 mg  Alecensa®  Roche Products Pty Ltd | Treatment of non-small cell lung cancer (NSCLC) | To compare the predicted and actual utilisation of alectinib for the treatment of NSCLC since PBS listing. |
| Sub-committee report  (DUSC Analysis) | DENOSUMAB  Injection 120 mg in 1.7 mL  Xgeva®  Amgen Australia Pty Ltd | Treatment of osteoporosis | To assess the utilisation of PBS listed denosumab for the treatment of osteoporosis. |
| Sub-committee report  (DUSC Analysis) | ECULIZUMAB  Solution concentrate for I.V. infusion 300mg in 30 mL  Soliris®  Alexion Pharmaceuticals Australasia Pty Ltd | Treatment of atypical haemolytic uraemic syndrome (aHUS) | To assess the utilisation of PBS listed eculizumab for the treatment of aHUS. |
| Sub-committee report  (DUSC Analysis) | IBRUTINIB  Capsule 140 mg  Imbruvia®  Janssen-Cilag Pty Ltd | Treatment of chronic lymphocytic leukaemia (CLL) and small lymphocytic lymphoma (SLL) | To compare the predicted and actual utilisation of ibrutinib for the treatment of CLL and SLL since PBS listing. |
| Sub-committee report  (DUSC Analysis) | OCRELIZUMAB  Solution concentrate for I.V. infusion 300 mg in 10 mL  Ocrevus®  Roche Products Pty Ltd | Treatment of relapsing-remitting multiple sclerosis (RRMS). | To compare the predicted and actual utilisation of ocrelizumab for the treatment of RRMS since PBS listing. |