PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2024 PBAC MEETING

Closing date for consumer comments 31 January 2024

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.

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- *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.

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.

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.)
ACCESS TO MEDICINES FOR PEOPLE IN CUSTODIAL SETTINGS VARIOUS MEDICINES DEPARTMENT OF HEALTH AND AGED CARE (Other matters)	Various medicines	The Department seeks to update the PBAC with advice received from the States and Territories concerning access to medicines for people in custodial settings and to seek further PBAC advice.

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ADALIMUMAB Injection 20 mg in 0.2 mL pre-filled syringe Injection 40 mg in 0.4 mL pre-filled syringe Injection 40 mg in 0.4 mL pre-filled pen Injection 80 mg 0.8 mL pre-filled syringe Injection 80 mg in 0.8 mL pre-filled pen Humira® ABBVIE PTY LTD (Change to existing listing)	Vision threatening non-infectious uveitis	Resubmission to request a General Schedule Authority Required (Telephone/Online) listing for the treatment of patients with vision-threatening non-infectious uveitis.
ADALIMUMAB Injection 20 mg in 0.2 mL pre-filled syringe Injection 40 mg in 0.4 mL pre-filled syringe Injection 40 mg in 0.4 mL pre-filled pen Injection 80 mg in 0.8 mL pre-filled syringe Injection 80 mg in 0.8 mL pre-filled pen Humira® ABBVIE PTY LTD (Change to existing listing)	Immune-mediated inflammatory disease	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of immune-mediated inflammatory disease in paediatric patients.

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ADALIMUMAB Injection 80 mg in 0.8 mL pre-filled pen Injection 80 mg in 0.8 mL pre-filled syringe Yuflyma® CELLTRION HEALTHCARE AUSTRALIA PTY LTD (New PBS listing)	Complex refractory fistulising Crohn disease Ulcerative colitis Crohn disease Chronic plaque psoriasis Hidradenitis suppurativa	To request General Schedule Authority Required (Written) listing of Yuflyma® 80 mg for initial and first continuing treatment, and Authority Required (STREAMLINED) listing for subsequent continuing treatment under the same conditions as its reference biologic Humira®.
AFLIBERCEPT Solution for intravitreal injection 11.34 mg in 100 microlitres (114.3 mg per mL) Solution for intravitreal injection 11.34 mg in 100 microlitres (114.3 mg per mL) pre-filled syringe Eylea® BAYER AUSTRALIA LTD (New PBS listing) TO BE CONSIDERED AT A FUTURE PBAC MEETING	Diabetic macular oedema (DMO)	To request a General Schedule Authority Required (Written) listing for the treatment of patients with visual impairment due to DMO.

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AFLIBERCEPT Solution for intravitreal injection 11.34 mg in 100 microlitres (114.3 mg per mL) Solution for intravitreal injection 11.34 mg in 100 microlitres (114.3 mg per mL) pre-filled syringe Eylea® BAYER AUSTRALIA LTD (New PBS listing) TO BE CONSIDERED AT A FUTURE PBAC MEETING	Subfoveal choroidal neovascularisation (CNV) secondary to age-related macular degeneration	To request a General Schedule Authority Required (Written) listing for the treatment of visual impairment caused by CNV secondary to age-related macular degeneration.
AMINO ACID FORMULA SUPPLEMENTED WITH PREBIOTICS, PROBIOTICS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS Oral powder 400 g (Neocate Syneo) Neocate® Syneo NUTRICIA AUSTRALIA PTY LIMITED (Other matters)	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 Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein Cows' milk anaphylaxis Severe intestinal malabsorption including short bowel syndrome Eosinophilic oesophagitis	To request Neocate® Syneo with new formulation continue to be listed on the PBS under the existing conditions.

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AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE Oral liquid 125 mL, 30 (PKU Lophlex Select LQ) PKU Lophlex® Select LQ NUTRICIA AUSTRALIA PTY LIMITED (New PBS listing)	Phenylketonuria (PKU)	To request a General Schedule Restricted Benefit listing for the dietary management of PKU.
AMINO ACID FORMULA WITH VITAMINS, MINERALS AND LONG CHAIN POLYUNSATURATED FATTY ACIDS WITHOUT PHENYLALANINE Oral powder 400 g (PKU Start) PKU Start™ VITAFLO AUSTRALIA PTY LIMITED (Other matters)	Phenylketonuria (PKU)	To request PKU Start with new formulation continue to be listed on the PBS under the existing conditions.

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ANIFROLUMAB Solution concentrate for I.V. infusion 300 mg in 2 mL 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 level of disease activity despite standard therapy.
ATEZOLIZUMAB Solution for subcutaneous injection containing atezolizumab 1875 mg in 15 mL Tecentriq® SC ROCHE PRODUCTS PTY LTD (New PBS listing)	Locally advanced or metastatic non-small cell lung cancer (NSCLC) Stage IV (metastatic) NSCLC Extensive-stage small cell lung cancer Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma Resected early stage (Stage II to IIIA) NSCLC	To request listing of a new form and strength of atezolizumab under the same conditions as the currently listed form and strengths of atezolizumab solution for intravenous (I.V.) infusion.

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AVACOPAN Capsule 10 mg Tavneos® SEQIRUS (AUSTRALIA) PTY LTD (New PBS listing)	Granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA)	Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for treatment of severe active granulomatosis with polyangiitis (GPA) and severe active microscopic polyangiitis (MPA) in combination with rituximab or cyclophosphamide.
BECLOMETASONE WITH FORMOTEROL Pressurised inhalation containing beclometasone dipropionate 100 micrograms and formoterol fumarate dihydrate 6 micrograms per dose,120 dose Fostair® CHIESI AUSTRALIA PTY LTD (Change to existing listing)	Asthma	To request a General Schedule Authority Required (STREAMLINED) listing as a maintenance and reliever treatment for asthma.

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BEVACIZUMAB Solution for I.V. infusion 100 mg in 4 mL Solution for I.V. infusion 400 mg in 16 mL Vegzelma® CELLTRION HEALTHCARE AUSTRALIA PTY LTD (New PBS listing)	Cancers	To request a Section 100 (Efficient Funding of Chemotherapy) Unrestricted Benefit listing of Vegzelma® under the same conditions as the PBS-listed bevacizumab biosimilars.
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)	Psoriatic arthritis (PsA)	To request a General Schedule Authority Required (Written) listing for the treatment of PsA.

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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)	Ankylosing spondylitis (AS)	To request a General Schedule Authority Required (Written) listing for the treatment of AS.
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)	Non-radiographic axial spondyloarthritis (nr-axSpA)	To request a General Schedule Authority Required (Written) listing for the treatment of nr-axSpA.

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BRENTUXIMAB VEDOTIN Powder for I.V. infusion 50 mg Adcetris® TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD. (Change to existing listing)	Hodgkin lymphoma	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (Telephone/Online) listing for the first-line treatment of advanced classical Hodgkin lymphoma.
BUDESONIDE Capsule (enteric) 3 mg Budenofalk® DR FALK PHARMA AUSTRALIA PTY LTD (New PBS listing)	Crohn disease (CD)	To request a General Schedule Authority Required (STREAMLINED) listing of a new form of budesonide for the treatment of mild to moderate CD.
BULEVIRTIDE Powder for injection 2 mg Hepcludex® GILEAD SCIENCES PTY LIMITED (New PBS listing)	Chronic hepatitis D	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listing for the treatment of chronic hepatitis D.

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CABOZANTINIB Tablet 20 mg Tablet 40 mg Cabometyx® IPSEN PTY LTD (Change to existing listing)	Renal cell carcinoma (RCC)	To request a General Schedule Authority Required (STREAMLINED) listing, in combination with nivolumab, for the first-line treatment of advanced clear cell RCC.
CABOZANTINIB Tablet 20 mg Tablet 40 mg Tablet 60 mg Cabometyx® IPSEN PTY LTD (Change to existing listing)	Renal cell carcinoma (RCC)	To request an amendment to the existing General Schedule Authority Required (STREAMLINED) listing to remove the ‘clear cell variant’ histology requirement to allow treatment in patients with non-clear cell RCC.

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CABOZANTINIB Tablet 20 mg Tablet 40 mg Tablet 60 mg Cabometyx® IPSEN PTY LTD (Change to existing listing)	Differentiated thyroid cancer (DTC)	Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of locally advanced or metastatic DTC in patients who have progressed during or after prior vascular endothelial growth factor-targeted therapy.
CETUXIMAB Solution for I.V. infusion 100 mg in 20 mL Solution for I.V. infusion 500 mg in 100 mL Erbitux® MERCK HEALTHCARE PTY LTD (Change to existing listing)	Metastatic colorectal cancer (mCRC)	To request an increase of maximum amount for the existing listings of cetuximab to allow clinician choice of either weekly or fortnightly dosing regimen for the treatment of mCRC.

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DABRAFENIB Capsule 50 mg (as mesilate) Capsule 75 mg (as mesilate) Tablet (dispersible) 10 mg Tafinlar® TRAMETINIB Tablet 500 micrograms Tablet 2 mg Powder for oral solution 5 micrograms per mL (as dimethylsulfoxide), 97 mL Mekinist® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED (Change to existing listing)	Glioma	To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of paediatric patients with BRAF V600E mutation positive low grade glioma or high grade glioma, and to request new forms and strengths of dabrafenib and trametinib.

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DAPAGLIFLOZIN WITH SITAGLIPTIN Tablet containing dapagliflozin 10 mg with sitagliptin 100 mg Sidapvia® ASTRAZENECA PTY LTD (New PBS listing)	Type 2 diabetes mellitus (T2DM)	To request a General Schedule Authority Required (STREAMLINED) listing, for use in combination with metformin, for the treatment of T2DM.
DAUNORUBICIN WITH CYTARABINE Powder for I.V infusion containing daunorubicin 44 mg and cytarabine 100 mg Vyxeos® JAZZ PHARMACEUTICALS ANZ PTY LTD (New PBS listing) WITHDRAWN	Acute myeloid leukaemia	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Telephone/Online) listing for the treatment of therapy-related acute myeloid leukaemia (t-AML) or acute myeloid leukaemia with myelodysplasia-related changes (AML-MRC) while system and IT challenges relating to a Section 100 (Efficient Funding of Chemotherapy) listing are resolved.

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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 existing listing)	Asthma	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of uncontrolled severe asthma in patients aged 6 to 11 years.
EDARAVONE Solution concentrate for injection I.V. infusion 30 mg in 20 mL Radicava® TEVA PHARMA AUSTRALIA PTY LTD (New PBS listing)	Amyotrophic lateral sclerosis (ALS)	Resubmission to request a Section 100 (Highly Specialised Drugs Program) Authority Required (Telephone/Online) listing for the treatment of ALS.

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ELEXACAFTOR WITH TEZACAFTOR AND WITH IVACAFTOR, AND IVACAFTOR Pack containing 56 sachets containing granules elexacaftor 100 mg with tezacaftor 50 mg and with ivacaftor 75 mg and 28 sachets containing granules ivacaftor 75 mg Pack containing 56 sachets containing graunules elexacaftor 80 mg with tezacaftor 40 mg and with ivacaftor 60 mg and 28 sachets containing granules ivacaftor 59.5 mg Trikafta® VERTEX PHARMACEUTICALS (AUSTRALIA) PTY. LTD. (New PBS listing)	Cystic fibrosis	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of cystic fibrosis in patients who are aged 2 to 5 years and who have at least one F508del mutation on the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene.
EMPAGLIFLOZIN Tablet 10 mg Jardiance® BOEHRINGER INGELHEIM PTY LTD (Change to existing listing)	Chronic heart failure	To request a change in the General Schedule Authority Required (STREAMLINED) listing for the treatment of chronic heart failure to allow treatment initiation by nurse practitioners.

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ETRASIMOD Tablet 2 mg Velsipity® PFIZER AUSTRALIA PTY LTD (New PBS listing)	Ulcerative colitis	To request a General Schedule Authority Required (Written) listing for the treatment of moderate to severe ulcerative colitis.
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 (Change to existing listing)	Hypercholesterolaemia	To request a change to the restriction level of the existing listings for initial treatment from Authority Required (Telephone/Online) to Authority Required (STREAMLINED). The submission also requested a change in the clinical criteria to reduce the minimum treatment duration required with both a statin and ezetimibe prior to initiating evolocumab.

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GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE Oral liquid 250 mL, 18 (PKU GMPro ULTRA LQ) PKU GMPro® ULTRA LQ NUTRICIA AUSTRALIA PTY LIMITED (New PBS listing) WITHDRAWN	Phenylketonuria (PKU)	To request a General Schedule Restricted Benefit listing for the dietary management of PKU in patients who are aged 3 years and over.
IBRUTINIB Capsule 140 mg Tablet 280 mg Tablet 420 mg Imbruvica® JANSSEN-CILAG PTY LTD (New PBS listing)	Chronic lymphocytic leukaemia (CLL) or Small lymphocytic lymphoma (SLL)	Resubmission to request a General Schedule Authority Required (Telephone/Online) listing, for use in combination with venetoclax, for the treatment of previously untreated CLL or SLL.

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ICOSAPENT ETHYL Capsule 1 g Vazkepa® SEQIRUS (AUSTRALIA) PTY LTD (New PBS listing)	Atherosclerotic cardiovascular disease with elevated triglycerides	Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for the treatment of atherosclerotic cardiovascular disease with elevated triglycerides.
INFLUENZA VACCINE Injection (0.5 mL) Flucelvax® Quad SEQIRUS (AUSTRALIA) PTY LTD (Change to existing listing)	Prevention of influenza	To request a National Immunisation Program listing for the prevention of influenza in patients aged 6 months and older.
INFLUENZA VACCINE Injection (0.5 mL) Flublok® Quadrivalent SANOFI-AVENTIS AUSTRALIA PTY LTD (New NIP listing)	Prevention of influenza	To request a National Immunisation Program listing for the prevention of influenza in patients aged 65 years and over.

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IRINOTECAN Solution for I.V. infusion containing nanoliposomal irinotecan (as sucrosofate) 43 mg in 10 mL Onivyde® SERVIER LABORATORIES (AUST.) PTY. LTD. (New PBS listing)	Pancreatic cancer	To request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing, for use in combination with oxaliplatin, 5-fluorouracil and folinic acid/leucovorin, for the first-line treatment of metastatic pancreatic adenocarcinoma.
LAROTRECTINIB Capsule 25 mg (as sulfate) Capsule 100 mg (as sulfate) Oral solution 20 mg per mL (as sulfate), 50 mL, 2 Vitrakvi® BAYER AUSTRALIA LTD (Change to existing listing)	Non-small cell lung cancer (NSCLC) or soft tissue sarcoma (STS) harbouring neurotrophic receptor tyrosine kinase (*NTRK*) gene fusions	Resubmission to request a General Schedule Authority Required (Written) listing for the treatment of locally advanced or metastatic NSCLC or STS harbouring *NTRK* gene fusions.

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LEBRIKIZUMAB Injection 250 mg in 2 mL single use autoinjector Ebglyss® ELI LILLY AUSTRALIA PTY LTD (New PBS listing)	Atopic dermatitis	To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of severe atopic dermatitis.
LEVODOPA WITH CARBIDOPA AND ENTACAPONE Intestinal gel containing levodopa 20 mg with carbidopa monohydrate 5 mg and with entacapone 20 mg per mL, 47 mL Lecigon® STADA PHARMACEUTICALS AUSTRALIA PTY LIMITED (New PBS listing)	Parkinson disease	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of advanced idiopathic Parkinson disease with severe motor fluctuations despite optimised alternative pharmacological treatment.

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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.)
MEPOLIZUMAB Powder for injection 100 mg Injection 100 mg in 1 mL single dose pre-filled pen Nucala® GLAXOSMITHKLINE AUSTRALIA PTY LTD (Change to existing listing)	Uncontrolled severe asthma	To request a change to the restriction level of the existing listings for initial treatment from Authority Required (Written) to Authority Required (Telephone/Online), and for continuing treatment from Authority Required (Written) to Authority Required (STREAMLINED) for the treatment of uncontrolled severe asthma. The submission also requested a change to the current requirement for treating with oral corticosteroids as part of optimised asthma therapy for the initial treatment of uncontrolled severe asthma.
MIGALASTAT Capsule containing migalastat hydrochloride 150 mg Galafold® AMICUS THERAPEUTICS PTY LTD (New PBS listing)	Fabry disease	To request the PBAC consider its previous recommendation to list migalastat as a General Schedule Authority Required (Written) listing for the treatment of Fabry disease, and to request an amendment to the restriction criteria to be consistent with international clinical guidelines for Fabry disease.

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NIVOLUMAB Injection concentrate for I.V. infusion 100 mg in 10 mL Injection concentrate for I.V. infusion 40 mg in 4 mL Opdivo® BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD (Change to existing listing)	Non-small cell lung cancer (NSCLC)	To extend the Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for the treatment of neoadjuvant treatment of resectable NSCLC to allow retreatment.
NIVOLUMAB Injection concentrate for I.V. infusion 100 mg in 10 mL Injection concentrate for I.V. infusion 40 mg in 4 mL Opdivo® BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD (Change to existing listing)	Muscle invasive urothelial carcinoma (MIUC)	To request reconsideration for a Section 100 (Efficient Funding of Chemotherapy) Authority Required (Telephone/Online) listing for the adjuvant treatment of high-risk MIUC. This matter was deferred at the November 2023 PBAC meeting.

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OFATUMUMAB Solution for injection 20 mg in 0.4 mL pre-filled pen Kesimpta® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED (Change to existing listing)	Multiple sclerosis	To request separating the current higher efficacy disease modifying therapies (DMT) tier into two distinct efficacy tiers.
OSILODROSTAT Tablet 1 mg Tablet 5 mg Isturisa® RECORDATI RARE DISEASES AUSTRALIA PTY. LTD. (New PBS listing)	Cushing syndrome	Resubmission to request the General Schedule Authority Required (Telephone/Online) listing for the treatment of endogenous Cushing syndrome.

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PEGCETACOPLAN Solution for intravitreal injection 15 mg in 0.1 mL (150 mg per mL) Syfovre® APELLIS AUSTRALIA PTY LTD (New PBS listing) WITHDRAWN	Geographic atrophy secondary to age related macular disease	To request a General Schedule Authority Required (Written) listing for the treatment of non-subfoveal geographic atrophy that is secondary to age-related macular degeneration.
PRASUGREL Tablet 5 mg Tablet 10 mg Prasugrel SCP GENERIC HEALTH PTY LTD (New PBS listing)	Acute coronary syndrome	To request a General Schedule Authority Required (STREAMLINED) listing, in combination with aspirin, for the treatment of acute coronary syndrome (myocardial infarction or unstable angina) managed by percutaneous coronary intervention.

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RAVULIZUMAB Solution concentrate for I.V. infusion 300 mg in 3 mL Solution concentrate for I.V. infusion 1,100 mg in 11 mL Ultomiris® ALEXION PHARMACEUTICALS AUSTRALASIA PTY LTD (New PBS listing) TO BE CONSIDERED AT A FUTURE PBAC MEETING	Generalised myasthenia gravis (gMG)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the treatment of adult patients with gMG who are anti-acetylcholine receptor antibody positive.
RELUGOLIX WITH ESTRADIOL AND WITH NORETHISTERONE ACETATE Tablet containing relugolix 40 mg with estradiol (as hemihydrate) 1 mg and with norethisterone acetate 0.5 mg Ryeqo® GEDEON RICHTER AUSTRALIA PTY LTD (New PBS listing)	Endometriosis	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of moderate to severe pain associated with endometriosis.

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RESPIRATORY SYNCYTIAL VIRUS VACCINE Injection (0.5 mL) Abrysvo® PFIZER AUSTRALIA PTY LTD (New NIP listing)	Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)	To request National Immunisation Program listing for the prevention of lower respiratory tract illness caused by RSV in infants from birth through to 6 months of age by active immunisation of pregnant individuals.
RIMEGEPANT Tablet (orally disintegrating) 75 mg Nurtec® ODT PFIZER AUSTRALIA PTY LTD (New PBS listing)	Acute migraine attacks	Resubmission to request a General Schedule Authority Required (STREAMLINED) listing for adults with migraine who have not responded adequately to treatment of at least two triptans.

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RISPERIDONE I.M. injection (modified release), set containing 1 pre-filled syringe powder for injection 75 mg and 1 pre-filled syringe diluent 383 microlitres I.M. injection (modified release), set containing 1 pre-filled syringe powder for injection 100 mg and 1 pre-filled syringe diluent 490 microlitres Okedi® MAXX PHARMA PTY LTD (New PBS listing)	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 existing listing)	Osteoporosis	To request the PBAC consider its previous recommendation to list romosozumab as a General Schedule Authority Required (Telephone/Online) listing for the treatment of severe osteoporosis in the first-line setting.

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SELUMETINIB Capsule 10 mg Capsule 25 mg Koselugo® ALEXION PHARMACEUTICALS AUSTRALASIA PTY LTD (New PBS listing)	Neurofibromatosis type 1 (NF1)	Resubmission to request a General Schedule Authority Required (Written) listing for the treatment of symptomatic, inoperable plexiform neurofibroma(s) in paediatric patients aged 2 years and over with NF1.
SIPONIMOD Tablet 1 mg (as hemifumarate) Mayzent® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED (New PBS listing)	Multiple sclerosis	To request a General Schedule Authority Required (STREAMLINED) listing of a new strength of siponimod for the treatment of relapsing-remitting multiple sclerosis.

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SODIUM ZIRCONIUM CYCLOSILICATE Sachet containing powder for oral suspension (as hydrate) 5 g Sachet containing powder for oral suspension (as hydrate) 10 g Lokelma® ASTRAZENECA PTY LTD (New PBS listing)	Chronic hyperkalaemia	To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of chronic hyperkalaemia in patients with chronic kidney disease Stage 3-4.
TADALAFIL Tablet 20 mg Tadalis CIPLA AUSTRALIA PTY LTD (New PBS listing)	Pulmonary arterial hypertension (PAH)	To request listing of a new pack size for tadalafil 20 mg of 60 tablets under the same conditions as the existing listings of the 56-pack size for the treatment of PAH.

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TALAZOPARIB Capsule 0.1 mg Capsule 0.25 mg Capsule 0.35 mg Capsule 0.5 mg Talzenna® PFIZER AUSTRALIA PTY LTD (New PBS listing)	Prostate cancer (PC)	To request a General Schedule Authority Required (STREAMLINED) listing, in combination with enzalutamide, for the treatment of metastatic castration resistant PC in patients with a Breast Cancer Gene 1 (*BRCA1*) or *BRCA2* mutation who have not received prior treatment with a novel hormonal agent.
TIOTROPIUM Capsule containing powder for oral inhalation 18 micrograms (as bromide monohydrate) Tiotropium Lupin GENERIC HEALTH PTY LTD (New PBS listing)	Chronic obstructive pulmonary disease (COPD)	To request a General Schedule Restricted Benefit listing of a new form of tiotropium for the treatment of COPD.

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TOFACITINIB Tablet (modified release) 11 mg Xeljanz® XR PFIZER AUSTRALIA PTY LTD (New PBS listing)	Rheumatoid arthritis (RA) Psoriatic arthritis (PsA)	To request listing of a new form and strength for tofacitinib under the same conditions as the existing listings of tofacitinib 5 mg for the treatment of severe active RA and severe PsA.
TRASTUZUMAB DERUXTECAN Powder for I.V. infusion 100 mg Enhertu® ASTRAZENECA PTY LTD (New PBS listing)	Human epidermal growth factor receptor 2 (HER2)-low breast cancer	Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required (Telephone/Online) listing for the treatment of patients with HER2-low unresectable or metastatic breast cancer.

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USTEKINUMAB Injection 45 mg in 0.5 mL single use pre-filled syringe Injection 45 mg in 0.5 mL single use pre-filled pen Injection 90 mg in 1 mL single use pre-filled syringe Injection 90 mg in 1 mL single use pre-filled pen Stelara® JANSSEN-CILAG PTY LTD (New PBS listing)	Psoriatic arthritis (PsA) Crohn disease (CD) Chronic plaque psoriasis (CPP) Ulcerative colitis (UC) Fistulising Crohn disease	To request Authority Required (Written) listing of new forms, and amendments to the current restrictions for severe CD and severe CPP to align with a change in the quantity required for adult patients resulting from the new listings.
USTEKINUMAB Injection 45 mg in 0.5 mL Injection 45 mg in 0.5 mL single use pre-filled syringe Injection 90 mg in 1 mL single use pre-filled syringe Solution for I.V. infusion 130 mg in 26 mL Wezlana® AMGEN AUSTRALIA PTY LIMITED (New PBS listing)	Psoriatic arthritis Crohn disease Chronic plaque psoriasis Ulcerative colitis	To request General Schedule and Section 100 (Highly Specialised Drugs Program) Authority Required (STREAMLINED) listings of ustekinumab biosimilar under the same conditions as its reference biologic.

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VEDOLIZUMAB Injection 108 mg in 0.68 mL single use pre-filled pen Powder for injection 300 mg Entyvio® TAKEDA PHARMACEUTICALS AUSTRALIA PTY. LTD. (Change to existing listing)	Crohn disease Ulcerative colitis	To request a change to the clinical criteria to allow an additional dose of vedolizumab 300 mg at Week 10 for the initial treatment of severe Crohn disease. The submission also requested the removal of the requirement to assess the risk of developing progressive multifocal leukoencephalopathy during this treatment from all PBS listings for vedolizumab.
VENETOCLAX Pack containing 14 tablets venetoclax 10 mg and 7 tablets venetoclax 50 mg and 7 tablets venetoclax 100 mg and 14 tablets venetoclax 100 mg Tablet 10 mg Tablet 50 mg Tablet 100 mg Venclexta® ABBVIE PTY LTD (Other matters) WITHDRAWN	Chronic lymphocytic leukaemia (CLL)	To request consideration of the current treatment duration and the eligible population being treated with venetoclax in the treatment of CLL.

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BECLOMETASONE WITH FORMOTEROL Pressurised inhalation containing beclometasone dipropionate 100 micrograms and formoterol fumarate dihydrate 6 micrograms per dose, 120 dose Fostair® Chiesi Australia Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Chronic obstructive pulmonary disease (COPD)	-
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 (Review of positive PBAC recommendations not accepted by applicants)	Plaque psoriasis	-

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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 (Review of positive PBAC recommendations not accepted by applicants)	Atopic dermatitis in children 6 to 11 years of age	-

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ENOXAPARIN Injection containing enoxaparin sodium 100 mg (10,000 I.U. anti-Xa) in 1 mL pre-filled syringe Injection containing enoxaparin sodium 120 mg (12,000 I.U. anti-Xa) in 0.8 mL syringe Injection containing enoxaparin sodium 150 mg (15,000 I.U. anti-Xa) in 1 mL syringe Injection containing enoxaparin sodium 20 mg (2,000 I.U. anti-Xa) in 0.2 mL pre-filled syringe Injection containing enoxaparin sodium 40 mg (4,000 I.U. anti-Xa) in 0.4 mL pre-filled syringe Injection containing enoxaparin sodium 60 mg (6,000 I.U. anti-Xa) in 0.6 mL pre-filled syringe Injection containing enoxaparin sodium 80 mg (8,000 I.U. anti-Xa) in 0.8 mL syringe Enoxapo® Apotex Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Antithrombotic	-

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FREMANEZUMAB Solution for injection 225 mg in 1.5 mL single dose pre-filled syringe Ajovy® Teva Pharma Australia Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Treatment-resistant migraine (change to maximum quantity and number of repeats)	-
GALCANEZUMAB Injection 120 mg in 1 mL pre-filled pen Emgality® Eli Lilly Australia Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Treatment-resistant high frequency episodic migraine	-

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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 (Review of positive PBAC recommendations not accepted by applicants)	Phenylketonuria	-
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 (Review of positive PBAC recommendations not accepted by applicants)	Phenylketonuria	-

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OZANIMOD Capsule 920 micrograms Pack containing 4 capsules 230 micrograms and 3 capsules 460 micrograms Zeposia® Celgene Pty Limited (Review of positive PBAC recommendations not accepted by applicants)	Ulcerative colitis	-
RABEPRAZOLE Tablet containing rabeprazole sodium 20 mg (enteric coated) Pariet® Janssen-Cilag Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Gastro-oesophageal reflux disease	-

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RISANKIZUMAB Injection 150 mg in 1 mL pre-filled syringe Injection 150 mg in 1 mL pre-filled pen Skyrizi® AbbVie Pty Ltd (Review of positive PBAC recommendations not accepted by applicants)	Psoriatic arthritis	-
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 (Review of positive PBAC recommendations not accepted by applicants)	New strength for Non-radiographic axial spondyloarthritis Severe active psoriatic arthritis Severe psoriatic arthritis Ankylosing spondylitis Active ankylosing spondylitis Severe chronic plaque psoriasis	-

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SOMAPACITAN Injection 10 mg in 1.5 mL pre-filled pen Sogroya® Novo Nordisk Pharmaceuticals Pty. Limited (Review of positive PBAC recommendations not accepted by applicants)	Adult-onset growth hormone deficiency	-
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 (Sub-committee report DUSC Analysis)	Severe asthma	To assess the utilisation of dupilumab for the treatment of uncontrolled severe asthma.

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NIVOLUMAB Injection concentrate for I.V. infusion 100 mg in 10 mL Injection concentrate for I.V. infusion 40 mg in 4 mL Opdivo® IPILIMUMAB Injection concentrate for I.V. infusion 200 mg in 40 mL Injection concentrate for I.V. infusion 50 mg in 10 mL Yervoy® BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD (Sub-committee report DUSC Analysis)	Mesothelioma	To assess the utilisation of nivolumab and ipilimumab for the treatment of unresectable malignant mesothelioma.

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PROGESTERONE All brands and strengths Various sponsors (Sub-committee report DUSC Analysis)	Prevention of preterm birth	To assess the utilisation of progesterone for the prevention of preterm birth.
ROMOSOZUMAB Injection 105 mg in 1.17 mL single use pre-filled syringe Evenity® AMGEN AUSTRALIA PTY LIMITED (Sub-committee report DUSC Analysis)	Osteoporosis	To assess the utilisation of romosozumab for the treatment of severe established osteoporosis.

OPIOID DEPENDENCE TREATMENT MEDICINES ACCESS BUPRENORPHINE Buvidal® Weekly Buvidal® Monthly CAMURUS PTY LYD Subutex® Sublocade® INDIVIOR PTY LTD BUPRENORPHINE WITH NALOXONE Suboxone® Film 2/0.5 Suboxone® Film 8/2 INDIVIOR PTY LTD METHADONE Aspen Methadone Syrup ASPEN PHARMACARE AUSTRALIA PTY LIMITED Biodone® Forte BIOMED AUST PTY LIMITED (Change to existing listing)	Opioid dependence	To provide the PBAC with an update on the transition of the ODT program to the Section 100 Highly Specialised Drugs (HSD) Program (Community Access), including feedback from stakeholders on the impacts of the maximum repeats that was set for these listings. To seek the advice of the PBAC on whether it would be appropriate to amend the circumstances under which ODT medicines are listed on the PBS.

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Items added or amended

1. ATEZOLIZUMAB (Tecentriq® SC) –Trade name amended
2. BIMEKIZUMAB (Bimzelx®) – Drug type and use amended
3. ELEXACAFTOR WITH TEZACAFTOR AND WITH IVACAFTOR, AND IVACAFTOR (Trikafta®) – Form amended
4. INFLUENZA VACCINE (Flublok® Quadrivalent) – Submission type amended
5. RESPIRATORY SYNCYTIAL VIRUS VACCINE (Abrysvo®) – Submission type amended
6. TIOTROPIUM (Tiotropium Lupin) – Form amended

Items added or amended previously

1. RAVULIZUMAB (Ultomiris®) – To be considered at a future PBAC meeting
2. DAUNORUBICIN WITH CYTARABINE (Vyxeos®) – Withdrawn
3. VENETOCLAX (Venclexta®) – Withdrawn
4. AFLIBERCEPT (Eylea®) - To be considered at a future PBAC meeting
5. AFLIBERCEPT (Eylea®) - To be considered at a future PBAC meeting
6. ACCESS TO MEDICINES FOR PEOPLE IN CUSTODIAL SETTINGS (Various medicines) – Added
7. CABOZANTINIB (Cabometyx®) – Added
8. TRAMETINIB (Mekinist®) – Form amended
9. EDARAVONE (Radicava®) – Added
10. ICOSAPENT ETHYL (Vazkepa®) – Added
11. RIMEGEPANT (Nurtec® ODT) – Added
12. RISPERIDONE (Okedi®) – Added
13. TIOTROPIUM (Tiotropium Lupin™) – Added
14. TRASTUZUMAB DERUXTECAN (Enhertu®) – Added
15. BECLOMETASONE WITH FORMOTEROL (Fostair®) - Review of positive PBAC recommendations not accepted by applicants – Added
16. BIMEKIZUMAB (Bimzelx®) - Review of positive PBAC recommendations not accepted by applicants – Added
17. DUPILUMAB (Dupixent®) - Review of positive PBAC recommendations not accepted by applicants – Added
18. ENOXAPARIN (Enoxapo®) - Review of positive PBAC recommendations not accepted by applicants – Added
19. FREMANEZUMAB (Ajovy®) - Review of positive PBAC recommendations not accepted by applicants – Added
20. GALCANEZUMAB (Emgavity®) - Review of positive PBAC recommendations not accepted by applicants – Added
21. GLYCOMACROPEPTIDE FORMULA WITH AMINO ACIDS, CARBOHYDRATES, MINERALS AND LOW PHENYLALANINE (PKU GMPro Mix-In®) - Review of positive PBAC recommendations not accepted by applicants – Added
22. GLYCOMACROPEPTIDE FORMULA WITH AMINO ACIDS, VITAMINS, MINERALS, TRACE ELEMENTS, CARBOHYDRATE, FAT AND LOW PHENYLALANINE (PKU GMPro Ultra®) - Review of positive PBAC recommendations not accepted by applicants – Added
23. OZANIMOD (Zeposia®) - Review of positive PBAC recommendations not accepted by applicants – Added
24. RABEPRAZOLE (Pariet®) - Review of positive PBAC recommendations not accepted by applicants – Added
25. RISANKIZUMAB (Skyrizi®) - Review of positive PBAC recommendations not accepted by applicants – Added
26. SEKUKINUMAB (Cosentyx®) - Review of positive PBAC recommendations not accepted by applicants – Added
27. SOMAPACITAN (Sogrova®) - Review of positive PBAC recommendations not accepted by applicants – Added
28. ADALIMUMAB (Humira®) – Purpose of submission amended
29. AFLIBERCEPT (Eylea®) – Form amended
30. AFLIBERCEPT (Eylea®) – Form amended
31. ANIFROLUMAB (Saphnelo®) – Form amended
32. BECLOMETASONE WITH FORMOTEROL (Fostair®) – Drug, form and purpose of submission amended
33. BRENTUXIMAB VEDOTIN (Adcetris®) – Form amended
34. DABRAFENIB (Tafinlar®) – Form and purpose of submission amended
    TRAMETINIB (Mekinist®) – Form and purpose of submission amended

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35. DAPAGLIFLOZIN WITH SITAGLIPTIN (Sidapvia®) – Form amended
36. DUPILUMAB (Dupixent®) – Form amended
37. ELEXACAFTOR WITH TEZACAFTOR AND WITH IVACAFTOR, AND IVACAFTOR (Trikafta®) – Drug and form amended
38. GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE (PKU GMPro ULTRA LQ) – Form and brand amended
39. INFLUENZA VACCINE (Flucelvax® Quad) – Drug, form and purpose of submission amended
40. INFLUENZA VACCINE (Flublok® Quadrivalent) – Drug and form amended
41. IRINOTECAN (Onivyde®) – Drug and form amended
42. LAROTRECTINIB (Vitrakvi®) – Form amended
43. LEBRIKIZUMAB (Ebglyss®) – Form amended
44. LEVODOPA WITH CARBIDOPA AND WITH ENTACAPONE (Lecigon®) – Form amended
45. MIGALASTAT (Galafold®) – Purpose of submission amended
46. OFATUMUMAB (Kesimpta®) – Form amended
47. OSILODROSTAT (Isturisa®) – Purpose of submission amended
48. PEGCETACOPLAN (Syfovre®) – Form amended
49. RELUGOLIX WITH ESTRADIOL AND WITH NORETHISTERONE ACETATE (Ryeqo®) – Drug and form amended
50. RESPIRATORY SYNCYTIAL VIRUS VACCINE (Abrysvo®) – Drug and form amended
51. SIPONIMOD (Mayzent®) – Form amended
52. SODIUM ZIRCONIUM CYCLOSILICATE (Lokelma®) – Form amended
53. USTEKINUMAB (Wezlana™) – Form amended
54. CABOZANTINIB (Cabometyx®) – Form amended
55. DAUNORUBICIN WITH CYTARABINE (Vyxeos®) – Added
56. EVOLOCUMAB (Repatha®) – Purpose of submission amended
57. GLYCOMACROPEPTIDE FORMULA WITH DOCOSAHEXAENOIC ACID AND LOW PHENYLALANINE (PKU GMPro ULTRA LQ) – Withdrawn
58. NIVOLUMAB (Opdivo®) – Added
59. PEGCETACOPLAN (Syfovre®) – Withdrawn
60. TOFACITINIB (Xeljanz® XR) – Form amended
61. OPIOID DEPENDENCE TREATMENT MEDICINES ACCESS (various medicines) – Added