PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
March 2027 PBAC MEETING

Closing date for consumer consultation 20 January 2027

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 (NIP).

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 listing 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
16 Delistings
17 Positive recommendations not accepted by applicants after 2 years

Your comments are welcome whether you are a patient, carer, member of the public, health professional or member of a consumer interest group. Comments on new drug submissions, changes to listings and resubmissions and other items on the agenda can now be made through the Office of Health Technology Assessment consultation hub at: https://ohta-consultations.health.gov.au/pbac/.

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)).

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Initial submissions are categorised broadly as:

- *Category 1 or 2:* Submissions to list new medicines on the Schedule of Pharmaceutical Benefits or to make substantial changes to current listings are generally classified as Category 1 or 2 submissions. These submissions require presentation of an economic evaluation.
- *Category 3 or 4:* Submissions that relate to new forms of previously listed products and changes to the conditions of use e.g. change in maximum quantity/repeats or clarifying the wording of a restriction (while not altering the intended use) are considered to be Category 3 or 4 submissions. These submissions do not usually require the presentation of an economic evaluation.

Resubmissions are categorised broadly as Standard Re-entry Pathway, Early Resolution Pathway, Early Re-entry Pathway or Facilitated Resolution Pathway. Submission categories and resubmission pathways are outlined in the Procedure Guidance.

The PBAC meeting agenda will be published in week 2 – 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.

Category 1, 2 and resubmissions

Drug Name, form(s), strength(s) and Sponsor, Submission type, PBS schedule (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, requested authority level** (Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased.)
ATEZOLIZUMAB Solution concentrate for I.V. infusion 840 mg in 14 mL Solution concentrate for I.V. infusion 1200 mg in 20 mL Solution for subcutaneous injection 1875 mg in 15 mL Tecentriq® ROCHE PRODUCTS PTY LTD Change to existing listing PBS General Schedule PBS Section 100 (Efficient Funding of Chemotherapy)	Colon cancer	To request listing of atezolizumab in combination with fluoropyrimidine and oxaliplatin based chemotherapy for six months followed by atezolizumab monotherapy for six months for the adjuvant (i.e. after surgery) treatment of patients with resected stage III deficient mismatch repair (dMMR) colon cancer. Authority Required (STREAMLINED)

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BEMPEDOIC ACID Tablet 180mg Nexletol® BEMPEDOIC ACID WITH EZETIMIBE Tablet 180mg bempedoic acid with 10 mg ezetimibe Nexlizet® SEQIRUS (AUSTRALIA) PTY LTD New PBS listing PBS General Schedule	Hypercholesterolaemia	Resubmission to request listing of bempedoic acid, as monotherapy and in combination with ezetimibe, for the treatment of adult patients with hypercholesterolaemia (heterozygous familial and non-familial) at high risk of a first cardiovascular event or with established symptomatic atherosclerotic cardiovascular disease who have statin intolerance or are on maximally tolerated statin therapy, and despite treatment with ezetimibe, continue to have low-density lipoprotein cholesterol (LDL-C) levels greater than 1.8 mmol/L. This item was previously considered by the PBAC at its July 2026 meeting. Authority Required (STREAMLINED)
CEMIPLIMAB Solution concentrate for I.V. infusion 350 mg in 7 mL Libtayo® MEDISON PHARMA AUSTRALIA PTY LIMITED Change to existing listing PBS Section 100 (Efficient Funding of Chemotherapy)	Cutaneous squamous cell carcinoma (CSCC)	To request listing of cemiplimab for the treatment of patients with CSCC at high risk of recurrence following surgical resection and radiotherapy. Authority Required (Telephone/Online)

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COSIBELIMAB Solution concentrate for I.V. infusion 300 mg in 5mL Unloxcyt® SUN PHARMA ANZ PTY LTD New PBS listing PBS Section 100 (Efficient Funding of Chemotherapy)	Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC)	To request listing of cosibelimab for the treatment of patients with metastatic or locally advanced CSCC who are not candidates for curative surgery or curative radiation. Authority Required (Telephone/Online)
DARATUMUMAB Solution for subcutaneous injection containing daratumumab 1800 mg in 15 mL Darzalex SC® JANSSEN-CILAG PTY LTD Change to existing listing PBS General Schedule PBS Section 100 (Efficient Funding of Chemotherapy)	Multiple myeloma (MM)	To request listing of daratumumab in combination with lenalidomide, bortezomib and dexamethasone for the treatment of newly diagnosed MM patients who are considered eligible for autologous stem cell transplantation. Authority Required (Telephone/Online)

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DEURUXOLITINIB Tablet 8 mg Leqselvi® SUN PHARMA ANZ PTY LTD New PBS listing PBS General Schedule	Alopecia areata	To request listing of deuruxolitinib for the treatment of adult patients with severe alopecia areata defined as a Severity of Alopecia Tool (SALT) score greater than or equal to 50 who are unsuitable or have failed to achieve an adequate response to optimised conventional therapies. Authority Required (Written)
EFBEMALENOGRASTIM ALFA Injection 20 mg in 1 mL single-use pre-filled syringe Ryzneuta® VITALIS THERAPEUTICS PTY LTD New PBS listing PBS Section 100 (Highly Specialised Drugs Program)	Chemotherapy-induced neutropenia	To request listing of efbemalenograstim for the prevention (and treatment) of CIN in adult patients treated with cytotoxic chemotherapy for malignancy. Authority Required (STREAMLINED)

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ENFORTUMAB VEDOTIN Powder for I.V. infusion 20 mg Powder for I.V. infusion 30 mg Padcev® ASTELLAS PHARMA AUSTRALIA PTY LTD Change to existing listing PBS Section 100 (Efficient Funding of Chemotherapy)	Muscle invasive bladder cancer (MIBC)	To request listing of enfortumab vedotin in combination with pembrolizumab for the perioperative treatment (i.e. before and after surgery) of patients with non-metastatic MIBC who are intending to undergo radical cystectomy (bladder removal surgery) and are eligible for cisplatin-based chemotherapy. Authority Required (STREAMLINED)
IPTACOPAN Capsule 200 mg Fabhalta® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED Change to existing listing PBS General Schedule	Complement 3 glomerulopathy (C3G)	Resubmission to request listing of iptacopan for the treatment of adult patients with biopsy-confirmed C3G with either native kidneys or disease recurrence following a kidney transplant. This item was previously considered by the PBAC at its November 2025 meeting. Authority Required (Written)

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LEUPRORELIN Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 7.5 mg, injection set Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 22.5 mg, injection set Eligard 1 month® Eligard 3 month® MUNDIPHARMA PTY LIMITED Change to existing listing PBS General Schedule	Treatment with gonadotrophin releasing hormone (GnRH) agonist	To request an unrestricted listing for Eligard 1 Month and Eligard 3 Month to support their use across a number of women's health conditions. Unrestricted

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LEUPRORELIN I.M. injection (modified release), powder for injection containing leuprorelin acetate 7.5 mg with diluent in pre-filled dual-chamber syringe I.M. injection (modified release), powder for injection containing leuprorelin acetate 22.5 mg with diluent in pre-filled dual-chamber syringe Lucrin Depot® 7.5 mg PDS Lucrin Depot® 3 Month PDS ABBVIE PTY LTD Change to existing listing PBS General Schedule	Treatment with a gonadotrophin releasing hormone (GnRH) agonist	To request an unrestricted listing for Lucrin Depot 7.5 mg and Lucrin Depot 3 Month to support their use across a number of women's health conditions. Unrestricted
MIRVETUXIMAB SORAVTANSINE Solution for I.V. infusion 100 mg in 20 mL vial Elahere® ABBVIE PTY LTD New PBS listing PBS Section 100 (Efficient Funding of Chemotherapy)	Epithelial ovarian, fallopian tube or primary peritoneal cancer	To consider the sponsor's revised proposal for listing mirvetuximab soravtansine for the treatment of patients with high grade epithelial ovarian, fallopian tube or primary peritoneal cancer in patients who have platinum-resistant disease and high folate receptor alpha (FRα) expression. This item was recommended by the PBAC at its November 2025 meeting. Authority Required (Telephone/Online)

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MOLNUPIRAVIR Capsule 200 mg Lagevrio® MERCK SHARP & DOHME (AUSTRALIA) PTY LTD Change to existing listing PBS General Schedule	SARS-CoV-2 infection	To request continuation of the listing of molnupiravir for the treatment of patients with mild to moderate COVID-19 who are at high risk of severe disease, based on updated effectiveness, safety and cost-effectiveness information as previously requested by the PBAC. Authority Required (STREAMLINED)
mRNA-1010 mRNA Influenza vaccine Injection 37.5 micrograms in 0.38 mL single dose pre-filled syringe mFLUSVIA® MODERNA AUSTRALIA PTY LTD New NIP listing National Immunisation Program (NIP)	Prevention of seasonal influenza	To request a NIP listing of mFLUSVIA for the prevention of seasonal influenza in adults aged 65 years and over.

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mRNA-1083 mRNA Influenza and mRNA COVID-19 Vaccine Injection containing 8.3 micrograms of each seasonal influenza mRNA and 6.7 micrograms of SARS-CoV-2 JN.1 mRNA in 0.32 mL single dose pre-filled syringe mCOMBRIAX® MODERNA AUSTRALIA PTY LTD New NIP listing National Immunisation Program (NIP)	Prevention of seasonal influenza and coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2	To request a NIP listing of mCOMBRIAX for the prevention of seasonal influenza and coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 in adults aged 65 years and over.

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NAVEPEGRITIDE Powder for subcutaneous injection 0.6 mg (1.0 mg per mL) Powder for subcutaneous injection 1.3 mg (2.2 mg per mL) Powder for subcutaneous injection 2.8 mg (4.6 mg per mL) Powder for subcutaneous injection 5.5 mg (5.5 mg per mL) Yuviwel® SPECIALISED THERAPEUTICS PHARMA PTY LTD New PBS listing PBS General Schedule	Achondroplasia	To request listing of navepegritide for the treatment of patients with a diagnosis of achondroplasia confirmed by genetic testing, and whose epiphyses are not closed. Authority Required (Telephone/Online)
NIRMATRELVIR AND RITONAVIR Pack containing 4 tablets nirmatrelvir 150 mg and 2 tablets ritonavir 100 mg, 5 Paxlovid® PFIZER AUSTRALIA PTY LTD Change to existing listing PBS General Schedule	SARS-CoV-2 infection	To request continuation of the listing of nirmatrelvir and ritonavir for the treatment of patients with mild to moderate COVID-19 who are at high risk of severe disease, based on updated effectiveness, safety and cost-effectiveness information as previously requested by the PBAC. Authority Required (STREAMLINED)

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OBINUTUZUMAB Solution for I.V. infusion 1000 mg in 40 mL Gazyva® ROCHE PRODUCTS PTY LTD Change to existing listing PBS Section 100 (Highly Specialised Drugs Program)	Systemic lupus erythematosus (SLE)	To request listing of obinutuzumab for use as add-on treatment for patients with refractory SLE with persistent disease activity (supported by a SLE Disease Activity Index 2000 score of at least 10 points) despite standard therapy with hydroxychloroquine, immunosuppressant medication and prednisolone (or equivalent), unless contraindicated or intolerant. Authority Required (Telephone/Online)
OLUTASIDENIB Capsule 150 mg Rezlidhia® DR REDDY'S LABORATORIES (AUSTRALIA) PTY LTD New PBS listing PBS General Schedule	Acute myeloid leukaemia (AML)	To request listing of olutasidenib for the treatment of adult patients with relapsed or refractory AML with a susceptible IDH1 mutation (confirmed through a pathology report from an Approved Pathology Authority). Authority Required (Telephone/Online)

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PALBOCICLIB Tablet 75 mg Tablet 100 mg Tablet 125 mg Ibrance® PFIZER AUSTRALIA PTY LTD Change to existing listing PBS General Schedule	Breast cancer	To request listing of palbociclib, in combination with trastuzumab and/or pertuzumab plus endocrine therapy, for the maintenance treatment of patients with metastatic (Stage IV) hormone receptor (HR)–positive, human epidermal growth factor receptor (HER) 2–positive breast cancer who have received prior induction treatment with trastuzumab and pertuzumab plus a taxane without disease progression. Authority Required (Telephone/Online)
PEMIGATINIB Tablet 4.5 mg Tablet 9 mg Tablet 13.5 mg Pemazyre® SPECIALISED THERAPEUTICS ALIM PTY LTD New PBS listing PBS General Schedule	Locally advanced or metastatic cholangiocarcinoma (CCA)	To request listing of pemigatinib for the treatment of adult patients with locally advanced or metastatic CCA with a confirmed fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement who have progressed after at least one prior line of systemic therapy. Authority Required (STREAMLINED)

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POLATUZUMAB VEDOTIN Powder for I.V. infusion 30 mg Powder for I.V. infusion 140 mg Polivy® ROCHE PRODUCTS PTY LTD New PBS listing PBS Section 100 (Efficient Funding of Chemotherapy)	Diffuse large B-cell lymphoma (DLBCL)	To consider the sponsor's revised proposal for listing polatuzumab vedotin for use in combination with rituximab, cyclophosphamide, doxorubicin and prednisone for the treatment of patients with previously untreated DLBCL with an International Prognostic Index (IPI) score of 3-5. This item was recommended by the PBAC at its March 2025 meeting. Authority Required (Telephone/Online)
REMIBRUTINIB Tablet 25 mg Rhapsido® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED New PBS listing PBS General Schedule	Chronic spontaneous urticaria (CSU)	To request listing of remibrutinib for the treatment of adult patients with CSU who remain symptomatic despite treatment with a second-generation H1-antihistamine, for a maximum treatment course of 26 weeks. Patients who achieve a response, defined as a Urticaria Activity Score over 7 days (UAS7) of less than 16 by Week 26 may re-initiate treatment if their disease subsequently relapses to a UAS7 greater than or equal to 16. . Authority Required (Telephone/Online)

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RIMEGEPANT Tablet (orally disintegrating) 75 mg Nurtec® ODT PFIZER AUSTRALIA PTY LTD New PBS Listing PBS General Schedule	Acute migraine attacks	Resubmission to request listing of rimegepant for adult patients with eight or fewer moderate to severe acute migraine attacks per month, who are intolerant, contraindicated or who have had an inadequate response to analgesics and at least two triptans. This item was previously considered by the PBAC at its July 2023 and March 2024 meetings. Authority Required (STREAMLINED)
SECUKINUMAB Injection 150 mg in 1 mL pre-filled pen Cosentyx® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED Change to existing listing PBS General Schedule	Polymyalgia rheumatica (PMR)	To request listing of secukinumab for the treatment of adult patients aged 50 years or older with relapsing PMR, confirmed by a rheumatologist or clinical immunologist, who have relapsed within the previous 12 weeks while attempting to taper prednisone at a dose of at least 5 mg/day. Authority Required (Written) for initial treatment Authority Required (Telephone/Online) for continuing treatment

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TECLISTAMAB Solution for subcutaneous injection containing teclistamab 30 mg in 3 mL (10 mg per mL) Solution for subcutaneous injection containing teclistamab 153 mg in 1.7 mL (90 mg per mL) Tecvayli® JANSSEN-CILAG PTY LTD New PBS listing PBS General Schedule PBS Section 100 (Efficient Funding of Chemotherapy)	Relapsed or refractory multiple myeloma (RRMM)	To request listing of teclistamab, as monotherapy, for the treatment of patients with RRMM who have had progressive disease after receiving at least one prior line of therapy. Patients must not have previously received treatment with another B cell maturation antigen (BCMA) directed therapy for this condition. Authority Required (Telephone/Online)
TEZEPELUMAB Solution for injection 210 mg in 1.91 mL single dose pre-filled pen (110 mg per mL) Tezspire® ASTRAZENECA PTY LTD Change to existing listing PBS Section 100 (Highly Specialised Drugs Program)	Severe uncontrolled asthma	To request listing of tezepelumab for the treatment of patients aged 12 years or older with severe uncontrolled asthma who have elevated fractional exhaled nitric oxide (i.e. FeNO greater than or equal to 25 parts per billion (ppb)), do not meet the PBS criteria for eosinophilic or allergic asthma, and remain inadequately controlled despite optimised asthma therapy (i.e. adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months). Authority Required (Written)

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TOLEBRUTINIB Tablet 60 mg Cenrifki® SANOFI-AVENTIS AUSTRALIA PTY LTD New PBS listing PBS General Schedule	Multiple sclerosis	To request listing of tolebrutinib for the treatment of patients with non-relapsing secondary progressive multiple sclerosis. Patients must not have had clinical relapses for at least 24 months and must have evidence of disability progression in the previous 12 months. Authority Required (STREAMLINED)
TRASTUZUMAB DERUXTECAN Powder for I.V. infusion 100 mg Enhertu® ASTRAZENECA PTY LTD Change to existing listing PBS Section 100 (Efficient Funding of Chemotherapy Program)	Breast cancer	Resubmission to request listing of trastuzumab deruxtecan for the treatment of adult patients with hormone receptor positive (HR-positive) human epidermal growth factor receptor 2 (HER2)-low or HER2-ultralow unresectable and/or metastatic breast cancer who have received at least one prior line of endocrine therapy in the metastatic setting and are no longer suitable for further endocrine therapy. Authority Required (Telephone/Online)

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UPADACITINIB Tablet 15 mg Rinvoq® ABBVIE PTY LTD Change to existing listing PBS General Schedule	Active giant cell arteritis	To request listing of upadacitinib for use in combination with a 26 week corticosteroid tapering regimen for the treatment of adult patients aged 50 years or older with active giant cell arteritis. Authority Required (Written) for initial treatment Authority Required (Telephone/Online) for continuing treatment
VOSORITIDE Powder for injection 400 micrograms with diluent Powder for injection 560 micrograms with diluent Powder for injection 1.2 mg with diluent Voxzogo® BIOMARIN PHARMACEUTICAL AUSTRALIA PTY LTD Change to existing listing PBS General Schedule	Achondroplasia	To request continuation of the listing of vosoritide for the treatment of patients with achondroplasia who epiphyses are not closed, based on longer-term evidence to support its cost-effectiveness as previously requested by the PBAC. Authority Required (Telephone/Online)

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Other items

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TAFAMIDIS 61 mg capsule, 30 Vyndamax® Pfizer Australia Pty Ltd (Sub-committee report DUSC analysis)	Transthyretin amyloid cardiomyopathy	To review the utilisation of PBS listed tafamidis for transthyretin amyloid cardiomyopathy as requested by DUSC at its October 2026 meeting.
SEMAGLUTIDE 1.34 mg/mL injection, 1 x 3 mL pen device 0.68 mg/mL injection, 1 x 3 mL pen device Ozempic® Novo Nordisk Pharmaceuticals Pty. Limited DULAGLUTIDE 1.5 mg/0.5 mL injection, 4 x 0.5 mL pen devices Trulicity® Eli Lilly Australia Pty Ltd (Sub-committee report DUSC analysis)	Diabetes mellitus type 2	To review the use of glucagon-like peptide-1 (GLP-1) medicines for type 2 diabetes, including assessing whether the 1 June 2024 restriction changes have been effective in limiting GLP-1 use to the recommended population, as requested by DUSC at its June 2026 meeting.

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Drug Name, form(s), strength(s) and Sponsor, Submission type, PBS schedule (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, requested authority level** (Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased.)
DIFELIKEFALIN 50 microgram/mL injection, 12 x 1 mL vials Korsuva ® Seqirus (Australia) Pty Ltd (Sub-committee report DUSC analysis)	Moderate to severe pruritus (itching) associated with chronic kidney disease	To review the utilisation of PBS listed difelikefalin for the treatment of moderate to severe itching associated with chronic kidney disease as requested by DUSC at its October 2026 meeting.
Medicines for early breast cancer All brands and strengths Various sponsors (Sub-committee report DUSC analysis)	Early breast cancer	To review the utilisation of medicines for the treatment of early breast cancer as requested by DUSC at its October 2026 meeting.

PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
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Category 3, 4, and committee secretariat submissions

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ACALABRUTINIB Tablet 100 mg Calquence® ASTRAZENECA PTY LTD New PBS listing PBS General Schedule	Chronic lymphocytic leukaemia (CLL) / small lymphocytic lymphoma (SLL) Mantle cell lymphoma (MCL)	To request listing of a 60-tablet pack of acalabrutinib 100 mg across all listings, replacing the currently listed 56-tablet pack. Authority Required (Telephone/Online)
BUROSUMAB Injection 10 mg in 0.33 mL single dose pre-filled syringe Injection 20 mg in 0.67 mL single dose pre-filled syringe Injection 30 mg in 1.0 mL single dose pre-filled syringe Crysvita® KYOWA KIRIN AUSTRALIA PTY LTD New PBS listing PBS Section 100 (Highly Specialised Drugs Program)	X-linked hypophosphataemia (XLH) Tumour-induced osteomalacia (TIO)	To request listing of three new forms of burosumab consistent with the existing burosumab listings for XLH and TIO. Authority Required (Telephone/Online)

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CEMIPLIMAB Solution concentrate for I.V. infusion 350 mg in 7 mL Libtayo® MEDISON PHARMA AUSTRALIA PTY LIMITED Change to existing listing PBS Section 100 (Efficient Funding of Chemotherapy)	Advanced and metastatic cancers	To request a broad (multi-cancer) listing for cemiplimab as a treatment for immunotherapy-sensitive advanced or metastatic cancer. The proposed broad listing is intended to replace all existing PBS listings for cemiplimab in the advanced and metastatic setting. Authority Required (STREAMLINED)
FREMANEZUMAB Solution for injection 225 mg in 1.5 mL single dose pre-filled pen Solution for injection 225 mg in 1.5 mL single dose pre-filled syringe Ajovy® TEVA PHARMA AUSTRALIA PTY LTD Change to existing listing PBS General Schedule	Treatment-resistant migraine	To request an expansion of the current listing of fremanezumab for treatment-resistant migraine such that it can be used in adolescents aged 15-17 years who weigh greater than or equal to 45 kg and have experienced an inadequate response, intolerance or contraindication to at least two prior preventive migraine medicines. Patients must have experienced at least eight migraine headache days per month and less than 15, over a period of at least six months, prior to commencement of treatment with fremanezumab. Authority Required (STREAMLINED)

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OMALIZUMAB Injection 300 mg in 2.0 mL single dose pre-filled pen Injection 300 mg in 2.0 mL single dose pre-filled syringe Omlyclo® CELLTRION HEALTHCARE AUSTRALIA PTY LTD New PBS listing PBS Section 100 (Highly Specialised Drugs Program)	Severe chronic spontaneous urticaria Uncontrolled severe asthma	To request listing of two new forms of the Omlyclo biosimilar brand of omalizumab consistent with the existing omalizumab listings. Authority Required (STREAMLINED)
ROMOSOZUMAB Injection 105 mg in 1.17 mL single use pre-filled syringe Evenity® AMGEN AUSTRALIA PTY LIMITED Change to existing listing PBS General Schedule	Severe established osteoporosis	To request a change to the listing of romosozumab for severe established osteoporosis such that first-line treatment can be initiated by either a consultant physician or a general practitioner. The continuation criteria already permit both prescriber types and would remain unchanged. Authority Required (Telephone/Online)

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USTEKINUMAB Injection 45 mg in 0.5 mL single dose pre-filled pen Injection 90 mg in 1.0 mL single dose pre-filled pen Wezlana® AMGEN AUSTRALIA PTY LIMITED New PBS listing PBS General Schedule	Severe chronic plaque psoriasis Severe psoriatic arthritis Severe Crohn disease Complex refractory fistulising Crohn disease Moderate to severe ulcerative colitis	To request listing of two new forms of the Wezlana biosimilar brand of ustekinumab consistent with the existing ustekinumab listings. Authority Required
ZILUCOPLAN Injection 16.6 mg in 0.416 mL single use auto-injector, 7 Injection 23.0 mg in 0.574 mL single use auto-injector, 7 Injection 32.4 mg in 0.810 mL single use auto-injector, 7 Zilbrysq® UCB AUSTRALIA PROPRIETARY LIMITED New PBS listing PBS Section 100 (Highly Specialised Drugs Program)	Generalised myasthenia gravis (gMG)	To request listing of three new forms of zilucoplan consistent with the existing zilucoplan listings for gMG. Authority Required (Written)